- Study Director: Centocor Ortho Biotech Services, L.L.C. Clinical Trial, Centocor Ortho Biotech Services, L.L.C.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2007-09-06

First Submitted that Met QC Criteria
2007-09-06

First Posted (Estimated)
2007-09-10

Results Reporting Dates

Results First Submitted
2010-05-28

Results First Submitted that Met QC Criteria
2010-05-28

Results First Posted (Estimated)
2010-06-24

Study Record Updates

Last Update Submitted that met QC Criteria
2012-08-28

Last Update Posted (Estimated)
2012-09-03

Last Verified
2012-08

More Information

Terms related to this study

Keywords Provided by Centocor Ortho Biotech Services, L.L.C.

plaque psoriasis
psoriasis
infliximab
remicade
etanercept
enbrel
psunrise
C0168Z04

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Dermatologic Agents
Gastrointestinal Agents
Antirheumatic Agents
Infliximab

Study Documents

No study documents available

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Dose Ranging Study to Evaluate the Safety and Efficacy of GSK2586184 in Patients With Chronic Plaque Psoriasis

ClinicalTrials.gov ID **NCT01782664**

Sponsor GlaxoSmithKline

Information provided by GlaxoSmithKline (Responsible Party)

Last Update Posted 2017 08 03

Study Details Tab

Study Overview

Brief Summary

A multi centre, randomised, dose ranging study to evaluate the safety and clinical efficacy of GSK2586184 in patients with chronic plaque psoriasis.

Feedback

There will be 2 study cohorts (Cohorts A and B). Cohort A is the main study cohort, and this part of the study will be randomised, double blind and placebo controlled. Fifty six subjects will be randomised in Cohort A: 14 subjects in each treatment group: 100 mg, 200 mg or 400 mg GSK2586184, or placebo. Cohort B is an exploratory, open label investigation of the effect of 400 mg GSK2586184 on inflammatory gene expression in the skin and whole blood, and GSK2586184 concentrations in the skin. A maximum of 8 subjects will be included, and all subjects will take 400 mg GSK2586184.

In both Cohorts A and B, study medication will be administered orally (as tablets), twice daily, for up to 12 weeks.

Each subject will have 7 out patient visits: Screening; Baseline & Start of treatment; Week 2; Week 4; Week 8; Week 12; and Follow up (Week 16)

Official Title

A Multi centre, Randomised, Double blind, Placebo controlled, Dose Ranging Study to Evaluate the Safety and Efficacy of GSK2586184 in Patients With Chronic Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: 100 mg GSK2586184
- Drug: 200 mg GSK2586184
- Drug: 400 mg GSK2586184
- Drug: Placebo

Other Study ID Numbers

- 116679

Study Start

2013 03 01

Primary Completion (Actual)

2014 03 01

Study Completion (Actual)

2014 03 24

Enrollment (Actual)

68

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Germany

Berlin, Germany, 10117
GSK Investigational Site

Berlin, Germany, 10827
GSK Investigational Site

Berlin, Germany, 13507
GSK Investigational Site

Hamburg, Germany, 20354
GSK Investigational Site

Baden-Wuerttemberg Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Otherwise healthy subjects with a diagnosis of moderate to severe plaque psoriasis defined by the following criteria:
- Diagnosed for at least 12 months before the first dose of study medication
- Psoriasis plaques cover >=10% of body surface area.
- PASI score of >=12, and PGA score of>=3, and suitable for systemic or light therapy.
- Male or female, between 18 and 75 years of age inclusive.
- Female subjects of childbearing potential must agree to avoid pregnancy and male subjects must agree to avoid female partners becoming pregnant.
- Subjects must agree to use ultra violet (UV) light protection.
- Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form.

Exclusion Criteria:

- Unable to refrain from the use of the following prescription and non prescription drugs from the following periods before the first dose of study medication until completion of the follow up visit:
- 12 weeks: alefacept, ustekinumab, adalimumab, etanercept, infliximab, or certolizumab pegol
- 4 weeks or 5 half lives, whichever is longer:
- systemic medications for other medical conditions that are known to affect psoriasis, including but not limited to oral corticosteroids, cyclosporine, methotrexate, lithium, and beta adrenergic blockers
- 7 days or 5 half lives, whichever is longer:
- statins and other OATP and BCRP sensitive substrates (e.g. rapaglinide)
- any agent known to be a substrate of MATE1 and MATE2 K, which undergoes significant renal secretion (e.g. cimetidine)
- 3 weeks or 5 half lives, whichever is longer:
- any agent known to be a strong CYP3A4 inhibitor or inducer
- 2 weeks: topical therapies that are known to affect psoriasis, including but not limited to corticosteroids, retinoids, vitamin D derivatives, tar and anthralin
- Other medications (including vitamins, herbal and dietary supplements) will be considered on a case by case basis, and will be allowed if in the opinion of the investigator the medication will not interfere with the study procedures or compromise subject safety.
- Phototherapy within 4 weeks before the first dose of study medication.
- A live vaccination within 4 weeks before the first dose of study medication, or a live vaccination planned during the course of the study (until completion of the follow up visit).
- A major organ transplant (e.g. heart, lung, kidney, liver) or haematopoietic stem cell/marrow transplant.

- Significant unstable or uncontrolled acute or chronic disease unrelated to psoriasis (i.e. cardiovascular including uncontrolled hypertension, hypercholesterolemia, pulmonary, hematologic, gastrointestinal, hepatic, renal, neurological, malignancy or infectious diseases) which, in the opinion of the investigator, could confound the results of the study or put the subject at undue risk.
- A planned surgical procedure that, in the opinion of the investigator, makes the subject unsuitable for the study.
- A history of malignant neoplasm within the last 5 years, except for adequately treated cancers of the skin (basal or squamous cell) or carcinoma in situ of the uterine cervix.
- Acute or chronic infections, as follows:
- Known previous or active infection with Mycobacterium Tuberculosis
- Currently on any suppressive therapy for a chronic infection (such as pneumocystis, cytomegalovirus, herpes simplex virus, herpes zoster and atypical mycobacteria).
- Hospitalisation for treatment of infection within 60 days before first dose.
- Use of parenteral (IV or intramuscular) antibiotics (antibacterials, antivirals, antifungals, or antiparasitic agents) within 60 days before first dose.
- Unable to refrain from the consumption of grapefruit or grapefruit juice from 3 weeks before the first dose of study medication until 2 weeks after the last dose of study medication.
- History of sensitivity to any components of the study medications, or a history of drug or other allergy that, in the opinion of the investigator, contraindicates their participation.
- Serologic evidence of Hepatitis B (HB) infection based on the results of testing for HBsAg, anti HBc antibody as follows: subjects positive for HBsAg are excluded; and subjects positive for anti HBc antibody (regardless of anti HBs antibody status) are excluded.
- Positive test for Hepatitis C antibody confirmed sample with a Hepatitis C RIBA immunoblot assay or equivalent. Subjects who are positive for Hepatitis C antibody, but negative when the Hepatitis C RIBA immunoblot assay or equivalent test is performed will be eligible to participate. Subjects who are positive for Hepatitis C antibody and have a positive or indeterminate result when the Hepatitis C RIBA immunoblot assay or equivalent test is performed will not be eligible to participate.
- A positive test for HIV antibody.
- Pregnant females as determined by a positive serum hCG test at screening, or a positive urine hCG test pre dose on Day 1.
- Lactating females.
- Haemoglobin <11 g/dL, haematocrit <30%, WBC count (absolute) <3 × 10^9/L, neutrophils <1.5 × 10^9/L, platelets <100 × 10^9/L, lymphocytes <1 x 10^9/L.
- Current or history of renal disease, or estimated creatinine clearance <60 mL/min/1.73m^2 or serum creatinine >1.5 ULN.
- Single QTc > 450 msec; or QTc > 480 msec in subjects with Bundle Branch Block.
- Current or chronic history of liver disease, or known hepatic or biliary abnormalities (with the exception of Gilbert s syndrome or asymptomatic gallstones).
- ALT > 2xULN; alkaline phosphatase and bilirubin ≥ 1.5xULN (isolated bilirubin >1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%).
- History of regular alcohol consumption within 6 months of the study defined as an average weekly intake of >21 units for males or >14 units for females. One unit is

equivalent to 8 g of alcohol: a half pint (~240 ml) of beer, 1 glass (125 ml) of wine or 1 (25 ml) measure of spirits.

- The subject has participated in a clinical trial and has received an investigational product within 3 months before the first dose of study medication, or plans to take part in another clinical trial at the same time as participating in this clinical trial.

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 100 mg GSK2586184 Subjects will be randomized to 100 mg GSK2586184 twice daily for up to 84 days	Drug: 100 mg GSK2586184 • 100 mg GSK2586184 to be taken twice daily with food (as tablets) for up to 84 days.
Experimental: 200 mg GSK2586184 Subjects will be randomized to 200 mg GSK2586184 twice daily for up to 84 days	Drug: 200 mg GSK2586184 • 200 mg GSK2586184 to be taken twice daily with food (as tablets) for up to 84 days.
Experimental: 400 mg GSK2586184 Subjects will be randomized to 400 mg GSK2586184 twice daily for up to 84 days	Drug: 400 mg GSK2586184 • 400 mg GSK2586184 to be taken twice daily with food (as tablets) for up to 84 days.
Placebo Comparator: Placebo Subjects will be randomized to receive Placebo twice daily for up to 84 days	Drug: Placebo • Placebo tablets to be taken twice daily with food for up to 84 days.
Experimental: 400 mg GSK2586184 (Cohort B)	Drug: 400 mg GSK2586184 • 400 mg GSK2586184 to be taken twice daily with food (as tablets) for up to 84

Subjects will take 400 mg GSK2586184 twice daily for up to 84 days	days.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Had Achieved >=75% Improvement From Baseline in the Psoriasis Area Severity Index (PASI) Score at Week 12 (PASI 75)	PASI score was determined by evaluation of body surface area (BSA) covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no psoriasis) to 72(worse psoriasis). Final PASI=(sum of severity score for each area)x(% body affected score x area score). Baseline=Day 1. Percentage of participants who achieved >= 75% improvement from Baseline was reported with last observation carried forward (LOCF) analysis.	Baseline and Week 12
Percentage of Participants Who Had Achieved >=75% Improvement From Baseline	PASI score was determined by evaluation of BSA covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected	Baseline and Week 12

in the Psoriasis Area Severity Index (PASI) Score at Week 12 (PASI 75)	body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no psoriasis) to 72(worse psoriasis). Final PASI=(sum of severity score for each area)x(% body affected score x area score). Baseline=Day 1. Percentage of participants who achieved >= 75% improvement from Baseline was reported with LOCF analysis.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Any Adverse Event (AE) or Serious Adverse Event (SAE)	An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. A SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability or incapacity, is a congenital anomaly or birth defect. Any SAEs assessed as related to study participation (e.g. study treatment, protocol-mandated procedures, invasive tests, or change in existing therapy) or related to a GSK product was recorded from the time a participant consents to participate in the study up to and including any follow-up contact.	From Baseline (Day 1) until the Follow-up visit (Day 112)
Number of Participants With	Hematology parameters included: basophils, eosinophils, erythrocyte mean corpuscular	From BL (Day 1)

the Indicated Hematology Parameters Falling Outside of the Reference Range at Any Time Post-Baseline (BL) During Study	hemoglobin (EMCHb) EMCHb concentration (EMCHbC), erythrocyte mean corpuscular volume (EMCV), erythrocyte sedimentation rate (ESR), erythrocytes, hematocrit (fraction 1), hemoglobin, leukocytes, lymphocytes, monocytes, neutrophils, segmented neutrophils, platelets, reticulocytes. BL values were obtained at Day 1. The number of participants with the indicated hematology parameters data outside of the reference range (with high and low) any time post-BL are presented. Anytime post-BL assessments included any scheduled and unscheduled post-BL assessment.	until the Follow-up visit (Day 112)
Number of Participants With the Indicated Clinical Chemistry Parameters Falling Outside the Reference Range at Any Time Post-Baseline (BL) During the Study	Safety and tolerability were assessed by measuring the clinical chemistry parameters such as creatinine and cystatin C. BL values were obtained at Day 1. The number of participants with the indicated hematology parameter data outside of the reference range (> high or < low) at any time post-BL, including unscheduled or scheduled assessments, are presented.	From Baseline (Day 1) until the Follow-up visit (Day 112)
Number of Participants With the Systolic (S) and Diastolic (D) Blood Pressure (BP) Falling Outside the Clinical Concern Range at Any Time Post-baseline During the Study	Vital sign monitoring included systolic and diastolic BP measurements. BP measurements were taken in the supine position after 5 minutes of rest. The number of participants with the SBP or DBP outside the clinical concern range at any time post-BL are presented. SBP "low" was measured as less than 85 millimeters of mercury (mmHg)and "high" was measured as greater than 160 mmHg. DBP "low" was measured as less than 45 mmHg and "high" was measured as greater than 100 mmHg. The BL values were those values obtained at Day 1. Anytime post-BL	From Baseline (Day 1) until the follow-up visit (Day 112)

	assessments included any scheduled and unscheduled post-BL assessment.	
Number of Participants With the Heart Rate Falling Outside the Clinical Concern Range at Any Time Post-Baseline (BL) During the Study	Vital sign monitoring included heart rate (HR) measurements. HR measurements were taken in supine position after 5 minutes of rest. The number of participants with HR outside the clinical concern range at any time post-BL are presented. HR "low" was any HR less than 40 beats per minute (bpm) and "high" was any HR greater than 110 bpm. The BL values were those values obtained at Day 1. Anytime post-BL assessments included any scheduled and unscheduled post-BL assessment.	From Baseline (Day 1) until the Follow-up visit (Day 112)
Change From Baseline in Body Temperature	Vital sign monitoring included body temperature measurements. Body temperature measurements were taken in the supine position after 5 minutes of rest. Baseline is defined as the last result on or before the day of first dose. Change from Baseline was determined by subtracting the indicated time point value minus the Baseline value.	From Baseline (Day 1) until Week 16
Number of Participants With the Indicated Maximum Change From Baseline in the Electrocardiogram (ECG) Findings	ECG measurements were obtained using single 12-lead ECGs with the participant in a supine position after resting in this position for at least 10 minutes. The Baseline values were those values obtained Pre-dose on Day 1. The change from Baseline was the difference between post-Baseline and Baseline. The QT intervals (milliseconds [msec]) corrected for heart rate using Bazett s formula (QTcB) and Fridericia s formula (QTcF) are reported.	From Baseline (Day 1) until the Follow-up visit (Day 112)

Change From Baseline (BL) in the PASI Score at Week 2, 4, 8 and 12	Psoriatic lesions were assessed using the PASI. PASI score was determined by evaluation of BSA covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no psoriasis) to 72(worse psoriasis). Final PASI= (sum of severity score for each area)x(% body affected score x area score). Baseline=Day 1. The change from Baseline was the difference between post-Baseline and Baseline.	From Baseline (Day 1) until Week 12
PASI Score at Week 2, 4, 8 and 12	Psoriatic lesions were assessed using the PASI. PASI score was determined by evaluation of BSA covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no	Week 2, 4, 8 and 12

	psoriasis) to 72(worse psoriasis). Final PASI= (sum of severity score for each area)x(% body affected score x area score). Baseline=Day 1.	
Percentage of Participants Who Had a PASI Score With 50%, 75% and 90% Improvement From Baseline Until Week 12	Psoriatic lesions were assessed using the PASI. PASI score was determined by evaluation of BSA covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no psoriasis) to 72(worse psoriasis). Final PASI= (sum of severity score for each area)x(% body affected score x area score). Baseline was Day 1.	From Baseline (Day 1) until Week 12
Percentage of Participants Who Had a Physician Global Assessment (PGA) Score of Clear (0) or Almost Clear (1) at Weeks 2, 4, 8 and 12	The severity of psoriatic lesions over the whole body were assessed by the investigator using the PGA scoring system. A 0 to 6 point rating scale was used, as follows: 0 = Clear (no signs of psoriasis), 1 = Almost clear (slight elevation, scale and/or erythema), 2 = Mild (mild plaque elevation, scale and/or erythema), 3 = Mild to moderate (mild plaque elevation with moderate erythema and/or scale), 4 = Moderate (moderate plaque elevation, scale and/or erythema), 5 = Moderate to severe (marked plaque elevation, scale and/or erythema), 6 = Severe (very marked plaque elevation, scale and/or erythema). Higher scores indicated	Weeks 2, 4, 8 and 12

	worse psoriasis. The Baseline value was the value obtained on Day 1. The scores were reported with the last observation carried forward (LOCF) analysis.	
Percentage of Participants in Each PGA Score Category at Weeks 2, 4, 8 and 12	The severity of psoriatic lesions over the whole body were assessed by the investigator using the PGA scoring system. A 0 to 6 point rating scale was used, as follows: 0 = Clear (no signs of psoriasis), 1 = Almost clear (slight elevation, scale and/or erythema), 2 = Mild (mild plaque elevation, scale and/or erythema), 3 = Mild to moderate (mild plaque elevation with moderate erythema and/or scale), 4 = Moderate (moderate plaque elevation, scale and/or erythema), 5 = Moderate to severe (marked plaque elevation, scale and/or erythema), 6 = Severe (very marked plaque elevation, scale and/or erythema). Higher scores indicated worse psoriasis. The Baseline value was the value obtained on Day 1. The scores were reported with the last observation carried forward (LOCF) analysis.	Weeks 2, 4, 8 and 12
Time to PASI 75	PASI 75 was >= 75% improvement from Baseline in PASI score. Psoriatic lesions were assessed by the investigator using a PASI score. PASI score was determined by evaluation of BSA covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and	From Baseline (Day 1) until Week 12

	4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0(no psoriasis) to 72(worse psoriasis). Final PASI=(sum of severity score for each area)x(% body affected score x area score). Baseline was Day 1.	
Time to PGA Score of Clear (0) or Almost Clear (1)	The severity of psoriatic lesions over the whole body were assessed by the investigator using the PGA scoring system. A 0 to 6 point rating scale was used, as follows: 0 = Clear (no signs of psoriasis), 1 = Almost clear (slight elevation, scale and/or erythema), 2 = Mild (mild plaque elevation, scale and/or erythema), 3 = Mild to moderate (mild plaque elevation with moderate erythema and/or scale)4 = Moderate (moderate plaque elevation, scale and/or erythema), 5 = Moderate to severe (marked plaque elevation, scale and/or erythema), 6 = Severe (very marked plaque elevation, scale and/or erythema). The Baseline value was the value obtained on Day 1. The scores were reported with the last observation carried forward (LOCF) analysis.	From Baseline (Day 1) until Week 12
Change From Baseline in the Itch Visual Analogue Scale (VAS) Score at Week 2, 4, 8 and 12	The visual analogue scale (VAS) was used to assess itch. The participants rated the intensity of itch over the past week by marking a line on a 100 millimeter(mm) (0 to 100 mm) long scale. A line placed on the extreme left, that is 0 mm indicated no noticeable itching sensation and extreme right that is 100 mm indicated maximum itching sensation. This scale has no subscales. The participant perception of their symptoms was measured using the VAS itch score. The Baseline value was the value obtained on Day 1. The change from Baseline was the difference between post-Baseline and Baseline.	From Baseline (Day 1) until Week 12

Itch VAS Scores at Week 2, 4, 8 and 12	The visual analogue scale (VAS) was used to assess itch. The participants rated the intensity of itch over the past week by marking a line on a 100 mm (0 to 100 mm) long scale. A line placed on the extreme left, that is 0 mm indicated no noticeable itching sensation and extreme right that is 100 mm indicated maximum itching sensation. This scale has no subscales. The participant perception of their symptoms was measured using the VAS itch score. Itch VAS scores at Week 2, 4, 8 and 12 are reported.	Week 2, 4, 8 and 12
Change From Baseline of Dermatology Life Quality Index (DLQI) Score at Week 12	The DLQI was used to assess a participant s health-related quality of life. Participants completed the questionnaire to evaluate how their psoriasis affected their life over the week before the assessment took place. Each of the 10 questions was scored out of 0-3 as; 0 = Not at all, 1 = A little, 2 = A lot and 3 = Very much. The total score for the DLQI was calculated by adding up all the individual scores for each question resulting in a minimum of 0 and a maximum of 30. Higher score indicated worsening of participant s quality of life. The Baseline value was the value obtained on Day 1. The change from Baseline was the difference between post-Baseline and Baseline.	Baseline and Week 12
Population Pharmacokinetic (PK) Derived Area Under the Concentration-time Curve From Time Zero (Pre-dose) to the Time of the Last Measureable Concentration	Blood samples were taken to measure plasma concentrations of GSK2586184. A two-compartment model with a three-compartment transit model was used to derive PK parameters.	Baseline (pre-dose), Day 14 (2 to 3 hour and 3 to 4 hour post-dose), Day 28

(AUC(0-tau) of GSK2586184		(4 to 6 hour and 6 to 8 hour post-dose), Day 56 (at anytime during clinical visit), Day 84 (1 sample to be taken at anytime during clinical visit)
Clearance of GSK2586184	Blood samples were taken to measure plasma concentrations of GSK2586184. A two-compartment model with a three-compartment transit model was used to derive PK parameters.	Baseline (pre-dose), Day 14 (2 to 3 hour and 3 to 4 hour post-dose), Day 28 (4 to 6 hour and 6 to 8 hour post-dose), Day 56 (at

		anytime during clinical visit), Day 84 (1 sample to be taken at anytime during clinical visit)
Steady State Volume of Distribution (Vss) of GSK2586184	Blood samples were taken to measure plasma concentrations of GSK2586184. A two-compartment model with a three-compartment transit model was used to derive PK parameters.	Baseline (pre-dose), Day 14 (2 to 3 hour and 3 to 4 hour post-dose), Day 28 (4 to 6 hour and 6 to 8 hour post-dose), Day 56 (at anytime during clinical visit), Day 84 (1 sample to be

		taken at anytime during clinical visit)
Change From Baseline in Serum Neopterin Concentrations at Weeks 2, 4, 8 and 12	Serum Neopterin is a marker of psoriatic disease activity. Blood samples were collected for estimation of serum neoprotein concentration. Baseline was Day 1. The change from Baseline was the difference between post-Baseline and Baseline.	Baseline (pre-dose) and Weeks 2, 4, 8 and 12

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

GlaxoSmithKline

Collaborators

No information provided

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-01-31

First Submitted that Met QC Criteria
2013-01-31

First Posted (Estimated)
2013-02-04

Results Reporting Dates

Results First Submitted
2017-01-30

Results First Submitted that Met QC Criteria
2017-04-21

Results First Posted
2017-08-03

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-21

Last Update Posted
2017-08-03

Last Verified
2017-01

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline

PASI
DLQI
GSK2586184
plaque type psoriasis
PGA
inflammatory gene transcription
JAK 1 inhibitor
serum neopterin
skin biopsy
ACR response criteria
VAS itch score

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

Patient level data for this study will be made available through www.clinicalstudydatarequest.com following the timelines and process described on this site.

Study Data/Documents

1. Study Protocol (https://www.clinicalstudydatarequest.com)

   Information Identifier

   116679

   Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

2. Dataset Specification (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

3. Statistical Analysis Plan (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

4. Informed Consent Form (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

5. Individual Participant Data Set (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

6. Clinical Study Report (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

7. Annotated Case Report Form (https://www.clinicalstudydatarequest.com)

Information Identifier

116679

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by GlaxoSmithKline

Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research. (https://www.clinicalstudydatarequest.com)

Record 1 of 1

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Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Safety and Efficacy Study of Adalimumab in the Treatment of Plaque Psoriasis

ClinicalTrials.gov ID **NCT01646073**

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2015 01 19

Study Details Tab

Study Overview

Brief Summary

A study to evaluate the safety and efficacy of adalimumab in Chinese subjects with moderate to severe plaque psoriasis.

Feedback

Detailed Description

The purpose of this study is to evaluate the safety and efficacy of adalimumab and to determine how well it works in the treatment of adults with moderate to severe plaque psoriasis in the Chinese population. Psoriasis is a chronic immunologic disease characterized by marked inflammation and thickening of the epidermis that result in thick, scaly plaques involving the skin.

Official Title

A Phase 3, Randomized, Double Blind, Placebo Controlled, Multicenter Study to Assess the Safety and Efficacy of Adalimumab (Humira®) in Chinese Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Biological: Adalimumab
- Biological: placebo

Other Study ID Numbers

- M13 606

Study Start

2012 08

Primary Completion (Actual)

2013 12

Study Completion (Actual)

2013 12

Enrollment (Actual)

425

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

China

Beijing, China, 100034
Site Reference ID/Investigator# 72888

Beijing, China, 100044
Site Reference ID/Investigator# 72873

Beijing, China, 100730
Site Reference ID/Investigator# 72887

Chengdu, China, 610072
Site Reference ID/Investigator# 85693

Chongqing, China, 400038
Site Reference ID/Investigator# 72976



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Clinical diagnosis of psoriasis for at least 6 months.
- Must have stable plaque psoriasis for at least 2 months before screening and baseline visits.
- Participant must have a Psoriasis Area Severity Index score greater than or equal to 10 at the baseline visit.
- Participant must have moderate to severe plaque Psoriasis, defined by Body Surface Area involvement greater than or equal to 10% at the baseline visit.
- Participant must have a Physicians Global Assessment of at least moderate disease at baseline visit.

Exclusion Criteria:

- Diagnosis of other active skin diseases or skin infections.
- Participant has known hypersensitivity to adalimumab or it excipients.
- Participant has chronic recurring infections or active tuberculosis.
- Participant has demyelinating disease (including myelitis) or neurologic symptoms suggestive of demyelinating disease.
- Participant is known to have immune deficiency or is immunocompromised.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Adalimumab Adalimumab 40 mg every other week (eow)	Biological: Adalimumab • adalimumab eow • Other Names: ◦ ABT-D2E7 ◦ Humira
Placebo Comparator: Placebo placebo	Biological: placebo • placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a Psoriasis Area and Severity Index Greater Than or Equal to 75% Reduction	The percentage of participants with a greater than or equal to 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score at Week 12. PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower	Week 12

(PASI 75) Response at Week 12	extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible degree; a decrease in score indicates improvement.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a Psoriasis Area and Severity Index Greater Than or Equal to 75% Reduction (PASI 75) Response [Period A]	The percentage of participants with a greater than or equal to 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI), other than Week 12. PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible degree; a decrease in score indicates improvement.	Weeks 3 and 7
Percentage of Participants Achieving a Psoriasis Area and Severity Index Greater Than or Equal to 75% Reduction (PASI 75) Response [Period B]	The percentage of participants with a greater than or equal to 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI). PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible	Weeks 16, 19, and 24

	degree; a decrease in score indicates improvement.	
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score [Period A]	Psoriasis Area and Severity Index (PASI), is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible degree; a decrease in score indicates improvement.	Baseline to Week 12
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score [Period B]	PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible degree; a decrease in score indicates improvement.	Baseline to Week 24
Percentage of Participants Achieving a Psoriasis Area and Severity Index Greater Than or Equal to 50%, 90%, or 100% Reduction (PASI 50/90/100)	The percentage of participants with a greater than or equal to 50%, 90%, or 100% reduction (improvement) in Psoriasis Area and Severity Index (PASI 50/90/100). PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete	Weeks 3, 7, and 12

Response [Period A]	erythroderma of the severest possible degree; a decrease in score indicates improvement.	
Percentage of Participants Achieving a Psoriasis Area and Severity Index Greater Than or Equal to 50%, 90%, or 100% Reduction (PASI 50/90/100) Response [Period B]	The percentage of participants with a greater than or equal to 50%, 90%, or 100% reduction (improvement) in Psoriasis Area and Severity Index (PASI 50/90/100). PASI is a composite measure of the level of erythema (redness of the skin), induration (hardening of the skin), and desquamation (peeling of the skin) on 4 sites (head, upper extremities, trunk, and lower extremities), each of which are rated on a 5-point scale from 0 (no symptoms) to 4 (very marked). The possible range for PASI score is 0 to 72, with the highest score representing complete erythroderma of the severest possible degree; a decrease in score indicates improvement.	Weeks 16, 19, and 24
Percentage of Participants With a Physicians Global Assessment (PGA) of "Clear" [Period A]	The Physicians Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the physicians evaluation of the participant ranging from clear (meaning no signs of plaque) to severe.	Baseline and Weeks 3, 7, and 12
Percentage of Participants With a Physicians Global Assessment (PGA) of "Clear" [Period B]	The Physicians Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the physicians evaluation of the participant ranging from clear (meaning no signs of plaque) to severe.	Weeks 16, 19, and 24
Percentage of Participants With a Physicians	The Physicians Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the physicians evaluation	Baseline and Weeks 3,

Global Assessment (PGA) of "Clear" or "Minimal" [Period A]	of the participant ranging from clear (meaning no signs of plaque) to severe.	7, and 12
Percentage of Participants With a Physicians Global Assessment (PGA) of "Clear" or "Minimal" [Period B]	The Physicians Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the physicians evaluation of the participant ranging from clear (meaning no signs of plaque) to severe.	Weeks 16, 19, and 24
Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Score of "0" [Period A]	The DLQI measures how much a subjects skin problem affected their life over the last week. The possible range for DLQI was 0 to 30, with a higher score indicating a more impaired quality of life; a decrease in score indicates improvement.	Baseline, Week 3, and Week 12
Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Score of "0" [Period B]	The DLQI measures how much a participants skin problem affected their life over the last week. The possible range for DLQI was 0 to 30, with a higher score indicating a more impaired quality of life; a decrease in score indicates improvement.	Week 16 and Week 24

Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Score of "0 or 1" [Period A]	The DLQI measures how much a subject s skin problem affected their life over the last week. The possible range for DLQI was 0 to 30, with a higher score indicating a more impaired quality of life; a decrease in score indicates improvement.	Baseline, Week 3, and Week 12
Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Score of "0 or 1" [Period B]	The DLQI measures how much a participant s skin problem affected their life over the last week. The possible range for DLQI was 0 to 30, with a higher score indicating a more impaired quality of life; a decrease in score indicates improvement.	Week 16 and Week 24
Change From Baseline in the Short Form 36 (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) [Period A]	Short Form-36 is a generic 36-item questionnaire measuring health-related quality of life (HRQL) covering 2 summary measures: physical component summary (PCS) and mental component summary (MCS). The SF-36 consists of 8 subscales. The PCS is represented by 4 subscales: physical function, role limitations due to physical problems, bodily pain, and general health perception. The MCS is represented by 4 subscales: vitality, social function, role limitations due to emotional problems, and mental health. Participants self-report on items in a subscale that have choices per item. Summations of item scores of the same subscale give the subscale scores, which were transformed into a range from 0 to 100; zero= worst HRQL, 100=best HRQL. PCS and MCS scores were constructed as a T-score with a mean of 50 and standard deviation of 10 and no minimum or maximum score. The difference	Baseline to Week 12

	from baseline to week 12 in SF-36 PCS and MCS was calculated.	
Change From Baseline in the Short Form 36 (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) [Period B]	Short Form-36 is a generic 36-item questionnaire measuring health-related quality of life (HRQL) covering 2 summary measures: physical component summary (PCS) and mental component summary (MCS). The SF-36 consists of 8 subscales. The PCS is represented by 4 subscales: physical function, role limitations due to physical problems, bodily pain, and general health perception. The MCS is represented by 4 subscales: vitality, social function, role limitations due to emotional problems, and mental health. Participants self-report on items in a subscale that have choices per item. Summations of item scores of the same subscale give the subscale scores, which were transformed into a range from 0 to 100; zero= worst HRQL, 100=best HRQL. PCS and MCS scores were constructed as a T-score with a mean of 50 and standard deviation of 10 and no minimum or maximum score. The difference from baseline to week 12 in SF-36 PCS and MCS was calculated.	Baseline to Week 24

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

No information provided

Investigators

- Study Chair: Martin Okun, MD, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-07-18

First Submitted that Met QC Criteria
2012-07-18

First Posted (Estimated)
2012-07-20

Results Reporting Dates

Results First Submitted
2014-12-19

Results First Submitted that Met QC Criteria
2015-01-14

Results First Posted (Estimated)
2015-01-19

Study Record Updates

Last Update Submitted that met QC Criteria
2015-01-14

Last Update Posted (Estimated)
2015-01-19

Last Verified
2015-01

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Plaque Psoriasis
Psoriasis
Placebo Controlled
Skin Disease
Double Blind

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related Info (http://www.rxabbvie.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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COMPLETED

Safety and Efficacy Study of A Novel Ointment to Treat Plaque Type Psoriasis

ClinicalTrials.gov ID **NCT00759161**

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2017 03 06

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to determine the safety and efficacy of AN2728 Ointment, 5%, compared to Ointment Vehicle in the treatment of plaque type psoriasis.

Feedback

Detailed Description

This is a multi center, randomized, double blind bilateral design. Patients will apply the test articles, AN2728 Ointment, 5%, and Ointment Vehicle twice daily. The assigned study medication will be applied to two comparable treatment targeted plaques identified at baseline. One test article will be applied to one plaque and the other test article to an anatomically distinct plaque. All efficacy evaluations will be measured from only the two plaques identified at the baseline visit.

Official Title

A Double Blind, Randomized Bilateral Study of the Safety and Efficacy of AN2728 Ointment, 5%, Versus Ointment Vehicle in the Treatment of Patients With Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: AN2728
- Drug: AN2728 Ointment Vehicle

Other Study ID Numbers

- AN2728 PSR 201
- C3291014 (Other Identifier) (OTHER: Pfizer)

Study Start

2007 11

Primary Completion (Actual)

2008 03

Study Completion (Actual)

2008 03

Enrollment (Actual)

35

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Crisaborole (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Crisaborole)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Mexico

Distrito Federal Locations

Mexico City, Distrito Federal, Mexico, 06700
IMIC

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Male or female >18 years of age at time of enrollment.
2. The clinical diagnosis of stable plaque psoriasis.
3. Two target plaques of similar severity
    1. ≥ 5 cm2 but ≤ 100 cm2 computed by multiplying the greatest diameter of the plaque by the diameter of the plaque perpendicular to the greatest diameter.
    2. Bilaterally located (right/left) plaques on the arms or plaques located on the upper and lower trunk. Plaques located on the trunk were to be separated by at least 10 cm and designated by the Investigator as either left/right or front/back.
    3. Target plaque severity score of 2 4 (mild to moderate).
4. Normal or not clinically significant screening laboratory results.
5. Subjects who were willing and able to apply study drug as directed, comply with study instructions, and commit to all follow up visits.
6. Subjects who had the ability to understand, agree to and sign the study Informed Consent Form (ICF) prior to initiation of any protocol related procedures.

Exclusion Criteria:

1. Any dermatological conditions that could interfere with clinical evaluations or any disease state or physical condition which might expose the patient to an unacceptable risk by study participation
2. Any underlying disease(s) or other dermatological conditions that require the use of exclusionary topical or systemic therapy (see below)
3. Known sensitivity to any of the components of the study medication
4. Spontaneously improving or rapidly deteriorating psoriatic plaques or pustular/exfoliative, guttate, erythrodermic or other non plaque form of psoriasis
5. Concomitant use of topical or systemic therapies that might alter the course of psoriasis
6. Females of child bearing potential. Females must be post menopausal (based on FSH levels) or surgically sterile (oophorectomy)
7. Washout periods of:
    1. Topical drugs that might alter the course of psoriasis: 2 weeks
    2. Oral retinoids: 8 weeks
    3. Non retinoid systemic drugs that might alter the course of psoriasis: 4 weeks
    4. PUVA: 4 weeks
    5. UVB therapy: 4 weeks
    6. Use of emollients/moisturizers on area(s) to be treated: 2 days prior to baseline visit
8. AIDS or AIDS related illness
9. Concurrent participation in another drug research study or within 30 days of enrollment
10. Use of lithium or hydroxychloroquine containing products (i.e. Plaquenil)

11. Use of a beta blocking medication (i.e. propranolol) if the dose has not been stabilized for at least 3 months

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: 1 AN2728 Ointment, 5%	Drug: AN2728 • AN2728 Ointment, 5%, twice daily for 4 weeks • Other Names: ◦ AN2728 Ointment, 5%
Placebo Comparator: 2 AN2728 Ointment Vehicle	Drug: AN2728 Ointment Vehicle • AN2728 Ointment Vehicle, twice daily for 4 weeks.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Greater Decrease in Overall Target Plaque Severity Score (OTPSS) at Day 28	OTPSS is a scale to assess plaque severity. Each target plaque was scored on a severity rating scale ranging from 0 (no plaque) to 8 (very severe plaque), where higher score indicated more severity of a plaque. In this outcome measure, percentage of participants with reduced OTPSS at Day 28 were reported and comparison of ointment and vehicle treated plaque was given as Ointment treated plaque versus (vs.) vehicle treated plaque and Vehicle treated plaque vs. ointment treated plaque .	Day 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Overall Target Plaque Severity Score (OTPSS) at Day 7,14, 21, 28 and 35	OTPSS is a scale to assess plaque severity. Each target plaque was scored on a severity scale ranging from 0 (no plaque) to 8 (very severe plaque), where higher score indicated more severity of a plaque.	Baseline (Day 1), Day 7,14, 21, 28, 35
Change From Baseline in Erythema at Day 7,14, 21, 28 and 35	Erythema is used to assess plaque severity. Investigator rated the clinical appearance of erythema on a severity scale, ranging from 0 (no color on plaque, no erythema) to 8 (extreme red color on plaque, severe erythema), where higher score indicated more severe condition.	Baseline (Day 1), Day 7,14, 21, 28, 35
Change From Baseline in Scaling at Day 7,14, 21, 28 and 35	Scaling is a scale to assess plaque severity. Investigator rated the clinical appearance of scaling on a severity scale, ranging from 0 (no scaling on plaque) to 8 (very thick scales on plaque), where higher score indicated more severe condition.	Baseline (Day 1), Day 7,14, 21, 28, 35
Change From Baseline in Plaque Elevation at Day 7,14, 21, 28 and 35	Plaque elevation is a scale to assess plaque severity. Investigator rated presence of plaque elevation on a severity scale ranging, from 0 (no plaque elevation) to 8 (very marked plaque elevation), where higher score indicated more severe condition.	Baseline (Day 1), Day 7,14, 21, 28, 35
Percentage of Participants With Greater Decrease in Overall Target Plaque Severity	OTPSS is a scale to assess plaque severity. Each target plaque was scored on a severity rating scale ranging from 0 (no plaque) to 8 (very severe plaque), where higher score indicated more severity of a plaque. In this outcome measure, percentage of participants with	Day 7,14, 21, 35

Score (OTPSS) at Day 7,14, 21 and 35	reduced OTPSS at Day 7, 14, 21 and 35 were reported and comparison of ointment and vehicle treated plaque was given as Ointment treated plaque vs. vehicle treated plaque and Vehicle treated plaque vs. ointment treated plaque .	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2008-09-23

First Submitted that Met QC Criteria
2008-09-23

First Posted (Estimated)
2008-09-25

Results Reporting Dates

Results First Submitted
2017-01-12

Results First Submitted that Met QC Criteria
2017-01-12

Results First Posted
2017-03-06

Study Record Updates

Last Update Submitted that met QC Criteria
2017-01-12

Last Update Posted
2017-03-06

Last Verified
2017-01

More Information

Terms related to this study

Keywords Provided by Pfizer

Plaque Type Psoriasis
Topical

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Study to Demonstrate Equivalent Efficacy and to Compare Safety of Biosimilar Etanercept (GP2015) and Enbrel (EGALITY)

ClinicalTrials.gov ID NCT01891864

Sponsor Sandoz

Information provided by Sandoz (Responsible Party)

Last Update Posted 2017 03 27

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to demonstrate equivalent efficacy of GP2015 and Enbrel® in patients with moderate to severe chronic plaque type psoriasis with respect to PASI 75 response rate at Week 12.

Feedback

Detailed Description

The purpose of this confirmatory safety and efficacy study (GP15 302) was to demonstrate equivalence in efficacy and similarity in safety and immunogenicity of GP2015 and Enbrel (EU authorized) in patients with moderate to severe chronic plaque type psoriasis and to evaluate the effects of repeated switching between GP2015 and Enbrel on efficacy, overall safety, and immunogenicity. Since only EU authorized Enbrel was utilized in this study, the use of the term "Enbrel" throughout this report describes EU authorized Enbrel only.

Official Title

A Randomized, Double blind, Multicenter Study to Demonstrate Equivalent Efficacy and to Compare Safety and Immunogenicity of a Biosimilar Etanercept (GP2015) and Enbrel® in Patients With Moderate to Severe Chronic Plaque type Psoriasis

Conditions

Chronic Stable Plaque Psoriasis

Intervention / Treatment

- Drug: GP2015 Etanercept
- Drug: Enbrel

Other Study ID Numbers

- GP15 302

Study Start

2013 06

Primary Completion (Actual)

2014 06

Study Completion (Actual)

2015 03

Enrollment (Actual)

531

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Bulgaria

- **Pleven, Bulgaria**
  Sandoz Investigational Site
- **Plovdiv, Bulgaria**
  Sandoz Investigational Site
- **Sofia, Bulgaria**
  Sandoz Investigational Site 1
- **Sofia, Bulgaria**
  Sandoz Investigational Site 2
- **Sofia, Bulgaria**
  Sandoz Investigational Site 3



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Men or women at least 18 years of age at time of screening
- Chronic plaque type psoriasis diagnosed for at least 6 months before baseline
- Moderate to severe psoriasis as defined at baseline by:
  - PASI score of 10 or greater and,
  - Investigator´s Global Assessment score of 3 or greater (based on a scale of 0 4) and,
  - Body Surface Area affected by plaque type psoriasis of 10% or greater
- Chronic plaque type psoriasis patients who have previously received phototherapy or systemic psoriasis therapy at least once or who are candidates for such therapies in the opinion of the investigator.

Exclusion Criteria:

- Forms of psoriasis other than chronic plaque type
- Drug induced psoriasis
- Ongoing use of prohibited treatments
- Previous exposure to etanercept
- Active ongoing inflammatory diseases other than psoriasis that might confound the evaluation of the benefit of treatment with etanercept

Other In /Exclusion criteria may apply

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: GP2015 Etanercept Solution for subcutaneous injection in pre-filled syringe. The drug is administered in a dose of 50 mg twice weekly for the first 12 weeks and 50 mg once weekly thereafter	Drug: GP2015 Etanercept • Sandoz has developed GP2015 Etanercept (Sandoz s code for the drug product containing the active ingredient etanercept) to be biosimilar to Enbrel. • Other Names: ◦ GP2015 ◦ Etanercept
Active Comparator: Enbrel ® Etanercept Solution for subcutaneous injection in pre-filled syringe. The drug is administered in a dose of 50 mg twice weekly for the first 12 weeks and 50 mg once weekly thereafter	Drug: Enbrel • Enbrel is used as reference product to GP2015. • Other Names: ◦ Etanercept

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PASI 75 Response Rate at Week 12 - GP2015 Etanercept vs. Enbrel ® Etanercept	The 95% CI for the Psoriasis Area and Severity Index (PASI) 75 response rate differences at Week12 between GP2015 Etanercept and Enbrel ® Etanercept. PASI 75 response: patients who achieved ≥ 75% improvement (reduction) in PASI score compared to baseline were defined as PASI 75 responders. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretic maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in PASI Score up to Week 12	The key secondary efficacy endpoint was the % change from baseline in PASI score up to Week 12. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretic maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity. Two approaches (longitudinal approach applying a Mixed Model Repeated Measures and Averaged Treatment Effect approach applying an ANCOVA model) were employed in order to calculate 2-sided 95% confidence intervals (CI) for the difference between the treatment groups.	12 weeks

PASI 50, 75 and 90 Response Rates	Percentage of patients achieving Psoriasis Area and Severity Index (PASI) 50, PASI 75, and PASI 90 responses at Week 12. PASI 50 response: patients who achieved ≥ 50% improvement (reduction) in PASI score compared to baseline were defined as PASI 50 responders .PASI 90 response: patients who achieved ≥ 90% improvement (reduction) in PASI score compared to baseline were defined as PASI 90 responders .	Week12
Injection Site Reactions	Percentage of patients with injection site reactions up to Week 52	Week52
Immunogenicity: Measurement of Rate of ADA Formations Against GP2015 Etanercept and Enbrel ® Etanercept	Immunogenicity was analyzed by the percentage of patients with positive anti-drug antibodies (ADA) to either GP2015 Etanercept or Enbrel ® up to Week 52.	Week 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Sandoz

Collaborators

- Hexal AG

Investigators

- Principal Investigator: Sascha Gerdes, MD, Klinik für Dermatologie, Venerologie und Allergologie Universitätsklinikum Schleswig Holstein, Kiel, Germany

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-06-24

First Submitted that Met QC Criteria
2013-06-28

First Posted (Estimated)
2013-07-03

Results Reporting Dates

Results First Submitted
2016-09-26

Results First Submitted that Met QC Criteria
2017-02-06

Results First Posted
2017-03-27

Study Record Updates

Last Update Submitted that met QC Criteria

2017-02-06

Last Update Posted

2017-03-27

Last Verified

2017-02

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Dermatologic Agents
Etanercept
GP2015

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Study Documents

No study documents available

C n ca Tr a s gov return to the CTG homepage

Go to the c ass c webs te

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our fu d sc a mer (https //c n ca tr a s gov/about s te/d sc a mer) for deta s

C n ca Tr a s gov s a webs te and on ne database of c n ca research stud es and nformat on about the r resu ts The Nat ona L brary of Med c ne (NLM) ma nta ns the webs te **The study sponsor or investigator submits information** about the r study to C n ca Tr a s gov and **is responsible for the safety, science, and accuracy** of any study they st

Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

COMPLETED

Non-interventional Study of the Effect of Smoking Status of the Patient on the Success of Etanercept Therapy in Psoriasis

ClinicalTrials.gov ID NCT02192164

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2017 06 28

Study Details Tab

Study Overview

Brief Summary

P ot observat ona study to descr be the re at onsh p between the smok ng status of a psor at c nd v dua and the success of etanercept therapy n psor as s treatment

Detailed Description

non ntervent ona study There s no samp ng

Official Title

Non ntervent ona Study Of The Effect Of Smok ng Status Of The Pat ent On The Success Of Etanercept Therapy n Psor as s

Conditions

P aque Psor as s

Intervention / Treatment

- Behav ora smok ng quest onna re

Other Study ID Numbers

- B1801365

Study Start

2013 11

Primary Completion (Actual)

2016 05

Study Completion (Actual)

2016 05

Feedback

Enrollment (Actual)

126

Study Type

Observat ona

Resource links provided by the National Library of Medicine

Med neP us (https //med nep us gov/) re ated top cs Psor as s (https //med nep us gov/psor as s htm) Smok ng (https //med nep us gov/smok ng htm)

Drug nformat on (https //da ymed n m n h gov/da ymed/) ava ab e for Etanercept (https //da ymed n m n h gov/da ymed/search cfm? abe type=human&query=

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

Hungary

Budapest, Hungary, H-1085
Semmelweis Universi y

Debrecen, Hungary, 4032
Debreceni Egye em Orvos es Egeszseg udomanyi Cen rum/Bor es Nemikor ani Klinika

Kaposvár, Hungary, H-7400
Somogy Megyei Kaposi Mór Ok a ó Kórház

Kecskemet, Hungary, 6000
Bacs Kiskun Megyei Onkormanyza Korhaza Szegedi udomanyegye em AOK Ok a o Korhaza

Miskolc, Hungary, 3529
Semmelweis Korhaz Rendeloin eze

C ck to v ew nteract ve map

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treati

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

Eligibility Criteria

Description

nc us on Cr ter a

C n ca d agnos s of chron c p aque type psor as s for at east 6 months as determ ned by the subjects med ca h story, and confirmat on of the d agnos s through phys ca exam nat on by the nvest gator Pat ents who are schedu ed by the r dermato og st to n t ate treatment w th Etanercept

Exc us on Cr ter a

Prev ous or current treatment w th ant psor at c b o og c drugs, such as etanercept, nfl x mab, ada mumab, ustek numab, a efacept, efa zumab Chron c or acute nfect ons requ r ng ntravenous or ora ant nfect ves w th n 14 days pr or to the Base ne v s t

Study Population

etanercept treated p aque psor as s pat ents

Ages Eligible for Study

18 Years to 99 Years (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Sampling Method

Non Probab ty Samp e

Study Plan

Th s sect on prov des deta s of the study p an, nc ud ng how the study s des gned and what the study s measur ng

How is the study designed?

Design Details

Observational Model : Other
Time Perspective: Prospect ve

Cohorts and Interventions

Intervention/Treatment
Behav ora smok ng quest onna re • pat ents fi n a smok ng quest onna re about the r smok ng hab ts

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description
Change From Base ne n Psor as s Assessment and Sever ty ndex (PAS) Score at Week 24	PAS score s the comb ned assessment of es on sever ty and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Body d v ded nto 4 sect ons (head and neck [h], arms [u], trunk [t], egs [ ]); each area scored by tse f and scores comb ned for fina PAS score For each sect on, percent body surface area (A) of sk n nvo ved was est mated 0 (no nvo vement) to 6 (90 100 percent nvo vement), sever ty est mated by c n ca s gns erythema (E), ndurat on ( ), sca ng (S); 5 po nt sca e 0 (no nvo vement) to 4 (very marked nvo vement) F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu +

	u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4

Secondary Outcome Measures

Outcome Measure	Measure Description
Change From Base ne n Psor as s Assessment and Sever ty ndex (PAS) Score at Week 12	PAS score s the comb ned assessment of es on sever ty and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Body d v ded nto 4 sect ons (head and neck [h], arms [u], trunk [t], egs [ ]); each area scored by tse f and scores comb ned for fina PAS score For each sect on, percent body surface area (A) of sk n nvo ved was est mated 0 (no nvo vement) to 6 (90 100 percent nvo vement), sever ty est mated by c n ca s gns erythema (E), ndurat on ( ), sca ng (S); 5 po nt sca e 0 (no nvo vement) to 4 (very marked nvo vement) F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4
Percentage of Part c pants W th a Psor as s Area and Sever ty ndex 75 (PAS 75) Response at Week 12 and 24	PAS score s the comb ned assessment of es on sever ty and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Body d v ded nto 4 sect ons (head and neck [h], arms [u], trunk [t], egs [ ]); each area scored by tse f and scores comb ned for fina PAS score For each sect on, percent body surface area (A) of sk n nvo ved was est mated 0 (no nvo vement) to 6 (90 100 percent nvo vement), sever ty est mated by c n ca s gns erythema (E), ndurat on ( ), sca ng (S); 5 po nt sca e 0 (no nvo vement) to 4 (very marked nvo vement) F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4 PAS 75 response was defined as at east a 75 percent (%) reduct on n PAS re at ve to Base ne
Percent Change From Base ne n Psor as s Assessment and Sever ty ndex (PAS) at Week 12 and 24	Percentage mprovement n PAS score from base ne was ca cu ated at Week 12 and 24 n terms of percent change from base ne PAS score s the comb ned assessment of es on sever ty and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Body d v ded nto 4 sect ons (head and neck [h], arms [u], trunk [t], egs [ ]); each area scored by tse f and scores comb ned for fina PAS score For each sect on, percent body surface area (A) of sk n nvo ved was est mated 0 (no nvo vement) to 6 (90 100 percent nvo vement), sever ty est mated by c n ca s gns erythema (E), ndurat on ( ), sca ng (S); 5 po nt sca e 0 (no nvo vement) to 4 (very marked nvo vement) F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4

Other Outcome Measures

Outcome Measure	Measure Description
Smok ng Hab t Quest onna re Smok ng Status of Part c pants	Smok ng hab t quest onna re that was conducted on Day 1, assessed the data on smok ng status of part c pants Smok ng status of part c pants was c ass fied as never smoked, current smokers, and former smokers Former smokers were defined as those part c pants who had stopped smok ng at east 1 year pr or to the study
Smok ng Hab t Quest onna re Mean Age of Part c pants at Wh ch C garette Smok ng Started and Qu tted	Smok ng hab t quest onna re that was conducted on Day 1, assessed the data on smok ng wh ch nc uded the age of part c pants at wh ch they started smok ng and the age at wh ch they qu tted smok ng Former smokers were defined as those part c pants who had stopped smok ng at east 1 year pr or to the study
Smok ng Hab t Quest onna re Mean Durat on of Smok ng Among Part c pants	Smok ng hab t quest onna re wh ch was conducted on Day 1, assessed the data on smok ng wh ch nc uded the mean durat on (n years) of smok ng among part c pants Former smokers were defined as those part c pants who had stopped smok ng at east 1 year pr or to the study

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona to make sure they meet spec fic qua ty contro standards before be ng posted on the pub c webs te

Study Registration Dates

First Submitted
2014-04-11

First Submitted that Met QC Criteria
2014-07-14

First Posted (Estimated)
2014-07-16

Results Reporting Dates

Results First Submitted
2017-04-11

Results First Submitted that Met QC Criteria
2017-04-11

Results First Posted
2017-06-28

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-11

Last Update Posted
2017-06-28

Last Verified
2017-04

More Information

Terms related to this study

Keywords Provided by Pfizer

p aque psor as s
smok ng
etanercept

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here. (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=B1801365&StudyName=Non ntervent ona %20Study%20of%20the%20Effect%20of%20Smok ng%20Status%20of%20the%20Pat ent%20on%20the%20Success%20of%20Etanercept%20Therapy

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study to Evaluate the Efficacy and Tolerability of Topical Therapies for the Condition of Plaque-Type Psoriasis

ClinicalTrials.gov ID **NCT00852761**

Sponsor Stiefel, a GSK Company

Information provided by GlaxoSmithKline (Stiefel, a GSK Company) (Responsible Party)

Last Update Posted 2012 04 23

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to determine the efficacy and safety of two different forms of a topical steroid (clobetasol propionate) in patients with plaque type psoriasis.

Feedback

Detailed Description

This study is being conducted to obtain efficacy and tolerability data for two clobetasol propionate therapies in the treatment of plaque type psoriasis. Subjects will be randomized to only one of the two therapies for treatment throughout the study.

Official Title

A Study to Evaluate Safety and Efficacy of Clobetasol Propionate for Treatment of Plaque Type Psoriasis in Adult Subjects.

Conditions

Plaque Type Psoriasis

Intervention / Treatment

- Drug: Olux E Foam
- Drug: Clobex lotion

Other Study ID Numbers

- 114569
- U0280 402

Study Start

2009 03

Primary Completion (Actual)

2009 06

Study Completion (Actual)

2009 08

Enrollment (Actual)

34

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Clobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Clobetasol+propionate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

North Carolina Locations

Winston-Salem, North Carolina, United States, 27157
Wake Forest University Health Sciences
Department of Dermatology

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Body surface area (BSA) affected with psoriasis between 4% and 20% .
- Target lesion of at least 2 cm^2 on the elbow and/or knee, with a score of 2 or 3 on the Psoriasis Grading Scale for Target Lesion.
- Elbow and/or knee plaque type psoriasis with a Psoriasis Global Assessment of mild or moderate (2 or 3).
- Definitive diagnosis of elbow and/or knee plaque type psoriasis.
- Capable of understanding and willing to provide a signed and dated written voluntary informed consent (and any local or national authorization requirements) before any protocol specific procedures were performed.
- Male or female, 18 years of age or older at the time that the consent form was signed.
- Able to complete the study and comply with study instructions.
- Female subjects of childbearing potential must have had a negative pregnancy test. Sexually active women of childbearing potential participating in the study must have been using a medically acceptable form of contraception.

Exclusion Criteria:

- Use of any emollient applied to psoriasis plaques treated with the study medication during the study.
- Other serious skin disorder or any chronic medical condition that is not well controlled.
- Female subjects who are pregnant, trying to become pregnant or lactating.
- Any major illness within 30 days prior to the baseline visit.
- Received any investigational drug or treatment within 30 days of the baseline visit or who are scheduled to receive an investigational drug or treatment other than the study products during the study.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Olux-E Foam Olux-E (clobetasol propionate 0.05%) foam	Drug: Olux-E Foam • Olux-E (clobetasol propionate 0.05%) foam. Starting at baseline, subjects were to apply twice daily Olux-E foam to the affected elbows and/or knees up to day 15.
Active Comparator: Clobex lotion Clobex (clobetasol propionate 0.05%) lotion.	Drug: Clobex lotion • Clobetasol propionate 0.05% lotion. Starting at baseline, subjects were to apply twice daily Clobex lotion to the affected elbows and/or knees up to day 15 • Other Names: ◦ clobetasol lotion ◦ Clobex

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
At Least a One Grade Improvement for the Target Psoriasis Lesion on the Elbow or Knee (Psoriasis Grading Scale)	Number of participants who achieved a minimum 1-grade improvement in elbow and/or knee lesion using the Psoriasis Grading Scale for Target Lesion Score: 0 = No evidence of scaling, erythema, or elevation. 1 = Minimal; occasional scale, faint erythema, slight elevation. 2 = Mild; fine scales, light red color, slight elevation. 3 = Moderate; coarse scales, moderate red coloration and elevation . 4 = Marked; thick scale, bright red coloration, marked elevation. 5 = Severe; very thick tenacious scale predominates, dusky to deep red coloration, very marked elevation.	Baseline to day 15

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
At Least 1 Grade Improvement Psoriasis Grading Scale	Number of participants who achieve a minimum one grade improvement or more in their elbow and/or knee target lesion as defined by the Psoriasis Grading Scale for Target Lesion. The scale is the same as used for the primary outcome (0 through 5).	Baseline, days 3 and 8
At Least a 2 Grade Improvement Psoriasis Grading Scale	Number of participants who achieve a minimum two grade improvement or more in their elbow and/or knee target lesion as defined by the Psoriasis Grading Scale for Target Lesion. The scale is the same as used for the primary outcome (0 through 5).	Baseline, days 3, 8, 15

At Least a 3 Grade Improvement Psoriasis Grading Scale	Number of participants who achieve a minimum of three grade improvement or more in their elbow and/or knee target lesion as defined by the Psoriasis Grading Scale for Target Lesion. The scale is the same as used for the primary outcome (0 through 5).	Baseline, days 3, 8, 15
At Least 1 Grade Improvement in the Psoriasis Global Assessment	Number of participants who acheive at least a 1 grade improvement in the Psoriasis Global Assessment. 0 = Clear; 1 = Almost Clear; 2 = Mild; 3 = Moderate; 4 = Severe.	Baseline, days 3, 8, 15
At Least a 2 Grade Improvement in the Psoriasis Global Assessment	Number of participants who acheive at least a 2 grade improvement in the Psoriasis Global Assessment. 0 = Clear; 1 = Almost Clear; 2 = Mild; 3 = Moderate; 4 = Severe.	Baseline, days 3, 8, 15
At Least a 3 Grade Improvement in the Psoriasis Global Assessment	Number of participants who acheive at least a 3 grade improvement in the Psoriasis Global Assessment. 0 = Clear; 1 = Almost Clear; 2 = Mild; 3 = Moderate; 4 = Severe.	Baseline, days 3, 8, 15
At Least 1 Grade Improvement in Subject s Global Assessment	Number of participants who achieve treatment success (minimum one grade improvement or more) in their elbow and/or knee target lesion as defined by the Subject s Global Assessment. 0 = My skin is completely clear, except for residual hyperpigmentation. 1 = My psoriasis is almost clear; patchy fine scaling may be present. 2 = My psoriasis is mild, with a small amount of psoriasis. 3 = My psoriasis is moderate, between	Baseline, days 3, 8, 15

	slight and definitely noticeable. 4 = My psoriasis is very noticeable. 5 = My psoriasis is severe with severe redness, thick scaling, plaques.	
At Least a 2 Grade Improvement in Subject s Global Assessment	Number of participants who achieve treatment success (minimum two grade improvement or more) in their elbow and/or knee target lesion as defined by the Subject s Global Assessment. 0 = My skin is completely clear, except for residual hyperpigmentation. 1 = My psoriasis is almost clear; patchy fine scaling may be present. 2 = My psoriasis is mild, with a small amount of psoriasis. 3 = My psoriasis is moderate, between slight and definitely noticeable. 4 = My psoriasis is very noticeable. 5 = My psoriasis is severe with severe redness, thick scaling, plaques.	Baseline, days 3, 8, 15
At Least a 3 Grade Improvement in Subject s Global Assessment	Number of participants who achieve treatment success (minimum three grade improvement or more) in their elbow and/or knee target lesion as defined by the Subject s Global Assessment. 0 = My skin is completely clear, except for residual hyperpigmentation. 1 = My psoriasis is almost clear; patchy fine scaling may be present. 2 = My psoriasis is mild, with a small amount of psoriasis. 3 = My psoriasis is moderate, between slight and definitely noticeable. 4 = My psoriasis is very noticeable. 5 = My psoriasis is severe with severe redness, thick scaling, plaques.	Baseline, days 3, 8, 15
Median Change in Psoriasis Grading Scale	Median improvement in elbow and/or knee lesion using the Psoriasis Grading Scale for Target Lesion Score: 0 = No evidence of scaling, erythema, or elevation. 1 = Minimal; occasional scale, faint erythema, slight elevation. 2 = Mild; fine scales, light red color, slight elevation. 3 = Moderate; coarse scales, moderate red coloration and elevation . 4 = Marked; thick scale, bright red coloration, marked elevation. 5 = Severe; very thick tenacious scale predominates,	Baseline, Days 3, 8, 15

	dusky to deep red coloration, very marked elevation.	
Dermatology Quality of Life - Symptoms and Feelings	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for questions 1 and 2. Score range from 0 to 6. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Dermatology Quality of Life - Daily Activities	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for questions 3 and 4. Score range from 0 to 6. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Dermatology Quality of Life - Leisure	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for questions 5 and 6. Score range from 0 to 6. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Dermatology Quality of Life - Work and School	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for questions 7. Score range from 0 to 3. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Dermatology Quality of Life - Personal Relationships	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions.	Baseline, Days 3, 8, 15

	Sum of scores for questions 8 and 9. Score range from 0 to 6. A higher score denotes a more impaired quality of life	
Dermatology Quality of Life - Treatment	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for question 10. Score range from 0 to 3. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Total Dermatology Life Quality Index (DLQI) Score	Dermatology Quality of Life (DLQI) measures quality of life for people with skin conditions. Sum of scores for all questions. Score range from 0 to 30. A higher score denotes a more impaired quality of life	Baseline, Days 3, 8, 15
Dermatology Life Quality Index (DLQI) Categories	Number of participants who indicated one of the following for total DLQI: 0-1 No effect on the patient s life; 2-5 Small effect on the patient s life; 6-10 Moderate effect on the patient s life; 11-20 Very large effect on the patient s life.	Days 3, 8, 15

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Stiefel, a GSK Company

Collaborators

- GlaxoSmithKline

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2009-02-25

First Submitted that Met QC Criteria
2009-02-26

First Posted (Estimated)
2009-02-27

Results Reporting Dates

Results First Submitted
2010-11-04

Results First Submitted that Met QC Criteria
2011-09-01

Results First Posted (Estimated)

2011-10-04

Study Record Updates

Last Update Submitted that met QC Criteria

2012-04-19

Last Update Posted (Estimated)

2012-04-23

Last Verified

2012-04

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Clobetasol

Study Documents

No study documents available

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Record 1 of 1

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C n ca Tr a s gov s a webs te and on ne database of c n ca research stud es and nformat on about the r resu ts The Nat ona L brary of Med c ne (NLM) ma nta ns the webs te **The study sponsor or investigator submits information** about the r study to C n ca Tr a s gov and **is responsible for the safety, science, and accuracy** of any study they st

Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

COMPLETED

A Long Term Study To Evaluate The Safety, Tolerability And Efficacy Of CP-690,550 In Patients With Moderate To Severe Plaque Psoriasis And/Or Psoriatic Arthritis

ClinicalTrials.gov ID NCT01519089

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2015 08 13

Study Details Tab

Study Overview

Brief Summary

The ma n object ve of th s study s to eva uate the ong term safety of CP 690,550 n pat ents be ng treated for moderate to severe p aque psor as s and/or psor at c arthr t s Th s study w a so to compare the efficacy of two ora doses of CP 690,550 (5 mg B D and 10 mg B D) after 16 weeks of treatment

Official Title

A Phase 3, Mu t S te, Random zed, Doub e B nd Study Of The Long term Safety, To erab ty And Efficacy Of 2 Ora Doses Of Cp 690,550 n Subjects W th Moderate To Severe P aque Psor as s And/or Psor at c Arthr t s

Conditions

Psor as s

Intervention / Treatment

- Drug CP 690,550
- Drug CP 690, 550

Other Study ID Numbers

- A3921137

Study Start

2012 03

Primary Completion (Actual)

2014 01

Study Completion (Actual)

2014 01

Feedback

Enrollment (Actual)

95

Study Type

ntervent ona

Phase

Phase 3

Resource links provided by the National Library of Medicine

Med neP us Genet cs (https //med nep us gov/genet cs/) re ated top cs Psor at c arthr t s (https //med nep us gov/genet cs/cond t on/psor at c arthr t s)

Med neP us (https //med nep us gov/) re ated top cs Arthr t s (https //med nep us gov/arthr t s htm) Psor as s (https //med nep us gov/psor as s htm) Psor at c Arthr t s (https //med nep us gov/psor at carthr t s htm)

Genet c and Rare D seases nformat on Center (https //rared seases nfo n h gov/gard) resources Chron c Graft Versus Host D sease (https //rared seases nfo n h gov/d seases/10964/chron c graft versus host d sease) Spondy arthropathy (https //rared seases nfo n h gov/d seases/4971/spondy arthropathy)

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

Japan

Fukuoka, Japan, 814-0180
Fukuoka Universi y Hospi al

Fukushima, Japan, 960-1295
Fukushima Medical Universi y Hospi al

Osaka, Japan, 550-0012
Nissay Hospi al

Tokyo, Japan, 105-8471
Jikei Universi y Hospi al

Hokkaido Locations

C ck to v ew nteract ve map

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treatments

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

Eligibility Criteria

Description

nc us on Cr ter a

- Are 20 years or o der and cons dered to be cand dates for system c or phototherapy

[Moderate to Severe P aque Psor as s]

- D agnosed for at east 12 months
- Have Psor as s Area and Sever ty ndex (PAS) score of 12 and p aque type psor as s cover ng at east 10% of body surface area (BSA)

[Psor at c Arthr t s]

- D agnosed for at east 6 months
- Meet the CASPAR (c ass ficat on cr ter a for Psor at c Arthr t s) cr ter a at screen ng;
- Have act ve arthr t s (≥3 tender/pa nfu jo nts on mot on and ≥3 swo en jo nts), and act ve p aque psor as s w th at east 2 cm n d ameter

Exc us on Cr ter a

- Non p aque or drug nduced forms of psor as s
- Cannot d scont nue current ora , njectab e or top ca therapy for psor as s/psor at c arthr t s or cannot d scont nue phototherapy (PUVA or UVB)
- any uncontro ed s gn ficant med ca cond t on

Ages Eligible for Study

20 Years and o der (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Study Plan

Th s sect on prov des deta s of the study p an, nc ud ng how the study s des gned and what the study s measur ng

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Random zed
Interventional Model : Para e Ass gnment
Masking : Quadrup e (Part c pant, Care Prov der, nvest gator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Exper menta CP 690,550 10 mg B D	Drug CP 690,550 • 10 mg B D, cont nuous treatment for 16 weeks under b nd ng, 10 mg B D, cont nuous treatment for 4 weeks and var ab e dose (5 mg or 10 mg), cont nuous treatment for 32 weeks
Exper menta CP690,550 5 mg B D	Drug CP 690, 550 • 5 mg B D, cont nuous treatment for 16 weeks under b nd ng, 10 mg B D, cont nuous treatment for 4 weeks and var ab e dose (5 mg or 10 mg), cont nuous treatment for 32 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Part c pants W th a Psor as s Area and Sever ty ndex 75 (PAS 75) Response at Week 16	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 75 response was defined as at east a 75 percent (%) reduct on n PAS at Week 16 re at ve to Base ne	Week 16
Percentage of Part c pants W th a Phys c an G oba Assessment (PGA) of Psor as s Score of 'C ear' or 'A most C ear' at Week 16	The PGA of psor as s s scored on a 5 po nt sca e, reflect ng a g oba cons derat on of the erythema, ndurat on, and sca ng across a psor at c es ons Average erythema, ndurat on, and sca ng are scored separate y over the who e body accord ng to a 5 po nt sever ty sca e (0 [no symptom] to 4 [severe symptom]) The tota score was ca cu ated as average of the 3 sever ty scores and rounded to the nearest who e number score to determ ne the PGA score and category (0=c ear; 1=a most c ear; 2=m d; 3=moderate; and 4=severe) PGA response was defined as 0 (c ear) or 1 (a most c ear)	Week 16
Proport on of Part c pants W th an Amer can Co ege of Rheumato ogy 20% (ACR20) Response at Week 16	ACR20 response greater than or equa to (>=) 20 percent (%) mprovement n tender jo nt count; >=20% mprovement n swo en jo nt count; and >=20% mprovement n at east 3 of 5 rema n ng ACR core measures part c pant assessment of pa n; part c pant g oba assessment of d sease act v ty; phys c an g oba assessment of d sease act v ty; se f assessed d sab ty (d sab ty ndex of the Hea th Assessment Quest onna re [HAQ]); and C React ve Prote n (CRP)	Week 16
Number of Part c pants W th Adjud cated Card ovacu ar Events	Adjud cated card ovascu ar events were assessed by nvest gators as ndependent rev ewers based on event documentat on nc ud ng hosp ta d scharge summar es, operat ve reports, c n c notes, ECGs, d agnost c enzymes, resu ts of other d agnost c tests, autopsy reports and death cert ficate nformat on; spec fic requ rements vary w th the event requ r ng adjud cat on	Base ne to Fo ow up
Number of Part c pants W th Ma gnancy Events _Week 0 Through Fo ow up	For a b ops es of potent a y ma gnant tumors, susp c ous ymphadenopathy, or poss b e extranoda LPD, the study s te requested the patho og st to send the or g na s des used to make the defin t ve d agnos s, anc ary study reports, and the patho og st's report to the centra aboratory for a b nded rev ew by a centra patho og st	Base ne to Fo ow up

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Part c pants W th a Psor as s Area and Sever ty ndex 75 (PAS 75) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 75 response was defined as at east a 75 percent (%) reduct on n PAS at the each v s t re at ve to Base ne	Week 2, 4, 8, 12, 20, 28, 40, 52

Percentage of Part c pants W th a Psor as s Area and Sever ty ndex 50 (PAS 50) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 50 response was defined as at east a 50 percent (%) reduct on n PAS at the each v s t re at ve to Base ne	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Part c pants W th a Psor as s Area and Sever ty ndex 90 (PAS 90) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 90 response was defined as at east a 90 percent (%) reduct on n PAS at the each v s t re at ve to Base ne	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
T me to Ach eve a Phys c an G oba Assessment (PGA) of Psor as s Score of 'C ear' or 'A most C ear'	The PGA of psor as s s scored on a 5 po nt sca e, reflect ng a g oba cons derat on of the erythema, ndurat on, and sca ng across a psor at c es ons Average erythema, ndurat on, and sca ng are scored separate y over the who e body accord ng to a 5 po nt sever ty sca e (0 [no symptom] to 4 [severe symptom]) The tota score was ca cu ated as average of the 3 sever ty scores and rounded to the nearest who e number score to determ ne the PGA score and category (0=c ear; 1=a most c ear; 2=m d; 3=moderate; and 4=severe) PGA response was defined as 0 (c ear) or 1 (a most c ear) Med an t me to ach eve a PGA response up to week 16 s reported The med an t me to event s est mated based on Kap an Me er product m t method Med an t me to event s not est mab e f the est mated probab ty of response by Week 16 s ess than 50%	Week 16
T me to Ach eve a Psor as s Area and Sever ty ndex 75 (PAS 75) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and "percent of BSA" affected PAS s a compos te scor ng by the nvest gator of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 75 response was defined as at east 75% reduct on n PAS re at ve to Base ne The med an t me to event s est mated based on Kap an Me er product m t method Med an t me to event s not est mab e f the est mated probab ty of response by Week 16 s ess than 50%	Week 16
T me to Ach eve a Psor as s Area and Sever ty ndex 50 (PAS 50) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and "percent of BSA" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 50 response was defined as at east 50% reduct on n PAS re at ve to Base ne The med an t me to event s est mated based on Kap an Me er product m t method Med an t me to event s not est mab e f the est mated probab ty of response by Week 16 s ess than 50%	Week 16

T me to Ach eve a Psor as s Area and Sever ty ndex 90 (PAS 90) Response	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and "percent of BSA" affected PAS s a compos te scor ng assessed by the nvest gator, of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 90 response was defined as at east 90% reduct on n PAS re at ve to Base ne The med an t me to event s est mated based on Kap an Me er product m t method Med an t me to event s not est mab e f the est mated probab ty of response by Week 16 s ess than 50%	Week 16
Percentage of Part c pants W th a Psor as s Area and Sever ty ndex (PAS) Score >= 125 Percent of the Base ne PAS Score	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng by the nvest gator of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Score	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng by the nvest gator of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Component Score	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected Bas c character st cs of psor at c es ons erythema, ndurat on, and sca ng (PAS components) are scored separate y for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]) accord ng to a 5 po nt sca e 0 (no nvo vement); 1 (s ght); 2 (moderate); 3 (marked); 4 (very marked) PAS component score range from 0 to 4, where h gher scores nd cate greater sever ty of psor at c es ons	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Part c pants W th a Phys c an G oba Assessment (PGA) of Psor as s Score of 'C ear' or 'A most C ear'	The PGA of psor as s s scored on a 5 po nt sca e, reflect ng a g oba cons derat on of the erythema, ndurat on, and sca ng across a psor at c es ons Average erythema, ndurat on, and sca ng are scored separate y over the who e body accord ng to a 5 po nt sever ty sca e (0 [no symptom] to 4 [severe symptom]) The tota score was ca cu ated as average of the 3 sever ty scores and rounded to the nearest who e number score to determ ne the PGA score and category (0=c ear; 1=a most c ear; 2=m d; 3=moderate; and 4=severe) PGA response was defined as 0 (c ear) or 1 (a most c ear)	Week 2, 4, 8, 12, 20, 28, 40, 52
Percentage of Part c pants n a Phys c an G oba Assessment (PGA) of Psor as s Score Category	The PGA of psor as s s scored on a 5 po nt sca e, reflect ng a g oba cons derat on of the erythema, ndurat on, and sca ng across a psor at c es ons Average erythema, ndurat on, and sca ng are scored separate y over the who e body accord ng to a 5 po nt sever ty sca e (0 [no symptom] to 4 [severe symptom]) The tota score was ca cu ated as average of the 3 sever ty scores and rounded to the nearest who e number score to determ ne the PGA score and category (0=c ear; 1=a most c ear; 2=m d; 3=moderate; and 4=severe)	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Percentage of Part c pants Ma nta n ng Psor as s Area and Sever ty ndex 75 (PAS 75) Response After Week 16	The PAS quant fies the sever ty of a part c pant's psor as s based on both, " es on sever ty" and the "percent of body surface area (BSA)" affected PAS s a compos te scor ng by the nvest gator of degree of erythema, ndurat on, and sca ng (each scored separate y) for each of 4 body reg ons (head and neck, upper mbs, trunk [nc ud ng ax ae and gro n], and ower mbs [nc ud ng buttocks]), w th adjustment for the percent of BSA nvo ved for each body reg on and for the proport on of the body reg on to the who e body The PAS score can vary n ncrements of 0 1 and range from 0 0 to 72 0, w th h gher scores represent ng greater sever ty of psor as s PAS 75 response was defined as at east a 75 percent (%) reduct on n PAS re at ve to Base ne Ma ntenance of PAS 75 response at Week 52 among part c pants ach ev ng PAS 75 response at Week 16 s reported	Week 20, 28, 40, 52
Percentage of Part c pants Ma nta n ng Phys c an G oba Assessment (PGA) of Psor as s Score of 'C ear' or 'A most C ear'	The PGA of psor as s s scored on a 5 po nt sca e, reflect ng a g oba cons derat on of the erythema, ndurat on, and sca ng across a psor at c es ons Average erythema, ndurat on, and sca ng are scored separate y over the who e body accord ng to a 5 po nt sever ty sca e (0 [no symptom] to 4 [severe symptom]) The tota score was ca cu ated as average of the 3 sever ty scores and rounded to the nearest who e number score to determ ne the PGA score and category (0=c ear; 1=a most c ear; 2=m d; 3=moderate; and 4=severe) PGA response was defined as 0 (c ear) or 1 (a most c ear) Ma ntenance of PGA response at Week 52 among part c pants ach ev ng PGA response at Week 16 s reported	Week 20, 28, 40, 52
Change From Base ne n Na Psor as s Sever ty ndex (NAPS) Score	The NAPS quant fies sever ty of na psor as s by eva uat ng the presence or absence of psor at c man festat ons on the na matr x (p tt ng, eukonych a, red spots on u unea, crumb ng) and na bed (onycho ys s, sp nter hemorrhages, subungua hyperkeratos s, o drop [sa mon patch dyschrom a]) Each finger na d v ded w th mag nary nes nto quadrants and scored for both na matr x and na bed psor as s (range from 0 [absence of psor as s] to 4 [presence of psor as s n a 4 quadrants]) The tota NAPS score equa s the sum of scores for a of the finger na s eva uated and ranges from 0 to 80 H gher scores = more severe psor as s	Week 8, 16, 20, 28, 40, 52
Number of Affected Na s	Na psor as s s eva uated by the presence or absence of psor at c man festat ons on the na matr x (p tt ng, eukonych a, red spots on u unea, crumb ng) and na bed (onycho ys s, sp nter hemorrhages, subungua hyperkeratos s, o drop [sa mon patch dyschrom a]) Tota number psor as s affected na s (presence of psor at c man festat ons on the na matr x/na bed) were assessed and reported	Base ne, Week 8, 16, 20, 28, 40, 52
tch Sever ty tem (S) Score	S assessed sever ty of tch (prur tus) due to psor as s S s a s ng e tem, hor zonta numer c rat ng sca e Part c pants were asked to rate "your worst tch ng due to psor as s over the past 24 hours" on a numer c rat ng sca e anchored by the terms "No tch ng" (0) and "Worst poss b e tch ng" (10) at the ends for post base ne t me po nts Base ne S s average of scores on 7 days pr or to start of study treatment	Base ne, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Dermato ogy L fe Qua ty ndex (DLQ) Score	The DLQ s a 10 tem genera dermato ogy quest onna re that assess hea th re ated qua ty of fe (da y act v t es, persona re at onsh ps, symptoms and fee ngs, e sure, work and schoo , and treatment) The DLQ tem response opt ons are rated by the part c pant from 0 (not at a /not re evant) to 3 (very much) w th a tota score range of 0 (best) to 30 (worst); h gher scores nd cate poor qua ty of fe	Base ne, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n 36 tem Short Form Hea th Survey Vers on 2, Acute (SF 36) Doma n Score	36 tem Short Form Hea th Survey (SF 36) s a standard zed survey eva uat ng 8 aspects of funct ona hea th and we be ng phys ca and soc a funct on ng, phys ca and emot ona ro e m tat ons, bod y pa n, genera hea th, v ta ty, menta hea th These 8 aspects are summar zed as phys ca and menta hea th summary scores The score range for the phys ca and menta hea th scores s 0 100 (100=h ghest eve of funct on ng)	Week (W) 16, 28, 52
Change From Base ne n 36 tem Short Form Hea th	36 tem Short Form Hea th Survey (SF 36) s a standard zed survey eva uat ng 8 aspects of funct ona hea th and we be ng phys ca and soc a funct on ng,	Week 16, 28, 52

Survey Vers on 2, Acute (SF 36) Component Summary Score	phys ca and emot ona ro e m tat ons, bod y pa n, genera hea th, v ta ty, menta hea th These 8 aspects are summar zed as phys ca and menta hea th summary scores The score range for the phys ca and menta hea th scores s 0 100 (100=h ghest eve of funct on ng)	
Work L m tat on Quest onna re (WLQ)	WLQ part c pant reported 25 tem sca e to eva uate degree to wh ch hea th prob ems nterfere w th an ab ty to perform job ro es a ong 4 d mens ons T me Management sca e (5 tems); Phys ca Demands sca e (6 tems); Menta nterpersona Demands Sca e (9 tems); Output Demands Sca e (5 tems) A the sca es ranged from 0 (m ted none of the t me) to 100 (m ted a of the t me) The WLQ ndex score s the we ghted sum of the scores from the 4 WLQ sca es (tota score 0 [no oss] to 100 [comp ete oss of work])	Base ne (BL), Week (W) 4, 16, 28, 52
Percentage of Part c pants W th a Pat ent G oba Assessment (PtGA) of Psor as s Score Category	The PtGA asks the part c pant to eva uate the overa cutaneous d sease at that po nt n t me on a s ng e tem, 5 po nt sca e (0=c ear [no psor as s]; 1=a most c ear; 2=m d; 3=moderate; 4=severe)	Base ne, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Jo nt Pa n Assessment (JPA)	The JPA assesses sever ty of jo nt pa n The JPA s a hor zonta numer c rat ng sca e Part c pants were asked to "se ect the number that best descr bes any jo nt pa n that part c pant may have exper enced over the past 24 hours" w th response opt ons rang ng from "0 no jo nt pa n" to "10 worst poss b e jo nt pa n "	Base ne, Week 4, 16, 28, 52
Percentage of Part c pants W th an Amer can Co ege of Rheumato ogy 20% (ACR20) Response	ACR20 response greater than or equa to (>=) 20 percent (%) mprovement n tender jo nt count; >=20% mprovement n swo en jo nt count; and >=20% mprovement n at east 3 of 5 rema n ng ACR core measures part c pant assessment of pa n; part c pant g oba assessment of d sease act v ty; phys c an g oba assessment of d sease act v ty; se f assessed d sab ty (d sab ty ndex of the Hea th Assessment Quest onna re [HAQ]); and C React ve Prote n (CRP)	Week 2, 4, 8, 12, 20, 28, 40, 52
Percentage of Part c pants W th an Amer can Co ege of Rheumato ogy 50% (ACR50) Response	ACR50 response greater than or equa to (>=) 50 percent (%) mprovement n tender jo nt count; >=50% mprovement n swo en jo nt count; and >=50% mprovement n at east 3 of 5 rema n ng ACR core measures part c pant assessment of pa n; part c pant g oba assessment of d sease act v ty; phys c an g oba assessment of d sease act v ty; se f assessed d sab ty (d sab ty ndex of the Hea th Assessment Quest onna re [HAQ]); and C React ve Prote n (CRP)	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Part c pants W th an Amer can Co ege of Rheumato ogy 70% (ACR70) Response	ACR70 response greater than or equa to (>=) 70 percent (%) mprovement n tender jo nt count; >=70% mprovement n swo en jo nt count; and >=70% mprovement n at east 3 of 5 rema n ng ACR core measures part c pant assessment of pa n; part c pant g oba assessment of d sease act v ty; phys c an g oba assessment of d sease act v ty; se f assessed d sab ty (d sab ty ndex of the Hea th Assessment Quest onna re [HAQ]); and C React ve Prote n (CRP)	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Tender/Pa nfu Jo nt Count	S xty e ght (68) jo nts were assessed by a rheumato og st nvest gator to determ ne the number of jo nts that were cons dered tender or pa nfu The response to pressure/mot on on each jo nt was assessed w th the fo ow ng sca e Present/Absent/Not Done/Not App cab e (for Art fic a or m ss ng jo nts)	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Swo en Jo nt Count	S xty s x (66) jo nts were assessed for swe ng by a rheumato og st nvest gator to determ ne the number of jo nts that were cons dered swe ng The response to pressure/mot on on each jo nt was assessed w th the fo ow ng sca e Present/Absent/Not Done/Not App cab e (for Art fic a or m ss ng jo nts)	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Pat ent Assessment of Arthr t s Pa n	Subjects assessed the sever ty of the r arthr t s pa n w th a 100 mm v sua ana og sca e (VAS) by p ac ng a mark on the sca e between 0 (no pa n) and 100 (the most severe pa n), wh ch corresponded to the magn tude of the r pa n	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Pat ent G oba Assessment of Arthr t s	Subjects answered the fo ow ng quest on, "Cons der ng the poss b e effects of the arthr t s, how are you fee ng today?" The subject's response was recorded w th a 100 mm v sua ana og sca e (VAS), where 0 = very we and 100 = very poor y	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Phys c an G oba Assessment of Arthr t s	The rheumato og st nvest gator assessed how the subject's overa arthr t s appeared at the t me of the v s t Th s was an eva uat on based on the subject's d sease s gns, funct ona capac ty and phys ca exam nat on, and was ndependent of the PGA of arthr t s The rheumato og st nvest gator's response was recorded a 100 mm v sua ana og sca e (VAS), where 0 = very good and 100 = very poor	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ C React ve Prote n (CRP)	The b ood samp es were co ected at each v s t for ana ys s of CRP w th an assay ana yzed by the centra aboratory	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Base ne n Amer can Co ege of Rheumato ogy (ACR) Component_ Hea th Assessment Quest onna re D sab ty ndex (HAQ D)	HAQ D part c pant reported assessment of ab ty to perform tasks n 8 categor es of da y v ng act v t es dress/groom; ar se; eat; wa k; reach; gr p; hyg ene; and common act v t es over past week Each tem scored on 4 po nt sca e from 0 to 3 0=no d fficu ty; 1=some d fficu ty; 2=much d fficu ty; 3=unab e to do Overa score was computed as the sum of doma n scores and d v ded by the number of doma ns answered Tota poss b e score range 0 3 where 0= east d fficu ty and 3=extreme d fficu ty	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona L brary of Med c ne (NLM) to make sure they meet spec fic qua ty contro standards before be ng posted on the pub c webs te

Study Registration Dates

First Submitted
2011-12-22

First Submitted that Met QC Criteria
2012-01-25

First Posted (Estimated)
2012-01-26

Results Reporting Dates

Results First Submitted
2015-01-08

Results First Submitted that Met QC Criteria
2015-08-06

Results First Posted (Estimated)
2015-08-13

Study Record Updates

Last Update Submitted that met QC Criteria
2015-08-06

Last Update Posted (Estimated)
2015-08-13

Last Verified
2015-08

More Information

Terms related to this study

Keywords Provided by Pfizer

chron c
severe
moderate
treatment
safety
efficacy
CP 690
550
P aque psor as s
Psor as s Vu gar s
Psor at c Arthr t s
tofac t n b
Xe janz

Additional Relevant MeSH Terms

Jo nt D seases
Muscu oske eta D seases
Sk n D seases, Papu osquamous
Sk n D seases
Spondy arthropath es
Spondy arthr t s
Spondy t s
Sp na D seases

Bone D seases
Arthr t s
Arthr t s, Psor at c
Psor as s
Janus K nase nh b tors
Prote n K nase nh b tors
Enzyme nh b tors
Mo ecu ar Mechan sms of Pharmaco og ca Act on
Tofac t n b

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=A3921137&StudyName=A%20Long%20Term%20Study%20To%20Eva uate%20The%20Safety%2C%20To erab ty%20And%20Efficacy%20Of%20CP 690%2C550%20 n%20Pat ents%20W th%20Moderate%20To%20Severe%20P aque%20Psor)

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Efficacy and Safety of Subcutaneous Secukinumab (AIN457) for Moderate to Severe Chronic Plaque-type Psoriasis Assessing Different Doses and Dose Regimens (SCULPTURE)

ClinicalTrials.gov ID **NCT01406938**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2015 05 19

Study Details Tab

Study Overview

Brief Summary

Feedback

This study will assess the safety and efficacy of two different doses and two different dose regimens of subcutaneous secukinumab in patients that have moderate to severe, chronic, plaque type psoriasis.

Official Title

A Randomized, Double blind, Multicenter Study of Subcutaneous Secukinumab, Assessing Psoriasis Area and Severity Index (PASI) Response and Maintenance of Response in Subjects With Moderate to Severe Chronic Plaque type Psoriasis on Either a Fixed Dose Regimen or on a Retreatment at Start of Relapse Regimen

Conditions

Moderate to Severe Plaque type Psoriasis

Intervention / Treatment

- Drug: AIN457 150mg
- Drug: AIN457 300mg

Other Study ID Numbers

- CAIN457A2304
- 2011 000767 27 (EudraCT Number)

Study Start

2011 08

Primary Completion (Actual)

2013 05

Study Completion (Actual)

2013 05

Enrollment (Actual)

967

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Fresno, California, United States, 93710
Novartis Investigative Site

Pasadena, California, United States, 91105
Novartis Investigative Site

Sacramento, California, United States, 95817
Novartis Investigative Site

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion criteria:

- Moderate and severe plaque type psoriasis diagnosed for at least 6 months.

Severity of disease meeting all of the following three criteria:

- PASI score of 12 or greater,
- Investigator s Global Assessment (IGA) score of 3 or greater
- Total body surface area (BSA) affected of 10% or greater.
- Inadequate control by prior use of topical treatment, phototherapy and/or systemic therapy.

Exclusion criteria:

- Current forms of psoriasis other than chronic plaque type psoriasis (for example, pustular, erythrodermic, guttate).
- Current drug induced psoriasis.
- Previous use of secukinumab or any drug that targets IL 17 or IL 17 receptor.
- Significant medical problems such as uncontrolled hypertension, congestive heart failure or a condition that significantly immunocompromises the subject.
- Hematological abnormalities.
- History of an ongoing, chronic or recurrent infectious disease, or evidence of untreated tuberculosis.
- History of lymphoproliferative disease or history of malignancy of any organ system within the past 5 years.
- Pregnant or nursing (lactating) women.
- Other protocol defined inclusion/exclusion criteria may apply.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457150 mg-Induction period Only(IPO) secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)	Drug: AIN457 150mg • (1 injection per dose) and placebo to secukinumab 150 mg • Other Names: ◦ secukinumab 150 mg
Experimental: AIN457 300 mg - IPO secukinumab- 2 x 150mg injections per dose	Drug: AIN457 300mg • secukinumab 150 mg (2 injections per dose) • Other Names: ◦ secukinumab
Experimental: AIN457 150 mg - Fixed Interval (FI) 1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection	Drug: AIN457 150mg • (1 injection per dose) and placebo to secukinumab 150 mg • Other Names: ◦ secukinumab 150 mg
Experimental: AIN457 300 mg FI 2 s.c. secukinumab 150 mg injections	Drug: AIN457 300mg • secukinumab 150 mg (2 injections per dose) • Other Names:

	◦ secukinumab
Experimental: AIN457 150 mg- Start of relapse (SoR) 1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection	Drug: AIN457 150mg • (1 injection per dose) and placebo to secukinumab 150 mg • Other Names: ◦ secukinumab 150 mg
Experimental: AIN457 300 mg- SoR 2 s.c. secukinumab 150 mg injections	Drug: AIN457 300mg • secukinumab 150 mg (2 injections per dose) • Other Names: ◦ secukinumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
For the Fixed Interval Group and the Start of Relapse (SoR) Group, the Percentage of Participants (Who Responded to Treatment at Week 12) Maintaining a 75% Improvement From Baseline	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, arms: 0.2 body: 0.3 legs: 0.4)	Week 40 , week 52

in Psoriasis Area and Severity Index (PASI) Score at Week 52		

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week 2, 4, 6, 8, 12	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of	Baseline, week 2, 3 , 4, 8, 12

	section(head:01, arms:0.2 body:0.3 legs:0.4)	
Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week at Week 16, 20, 24,28,32,36,40,44,48,and Week 52	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head:01, arms:0.2 body:0.3 legs:0.4)	Baseline, week 12,16,20,24,28,32,36,40,44,48 and week 52
Percent of Participants Achieving Psoriasis	PASI is a combined assessment of	Baseline, week 2, 4, 6, 8, 12

	Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Induction)	lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the			

	participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe	
Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Maintenance Period))	The IGA mod 2011 is a static scale, i.e., it refers exclusively to the participant s disease state at the time of the assessments and does not attempt a comparison to any of the participant s previous disease states at prior visits. The score ranges from 0 (clear) to 4 (severe. The score 0 is clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 is severe	Baseline, week 16,20,24,28,32,36,40,44,48, and Week 52
Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Induction)	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five	Baseline to week 2, 4, 8, 12

	domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state)	
Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Maintenance)	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.

	state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state)	
Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Induction)	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a	Baseline to week 2, 4, 8, 12

	sum of the 10 questions	
Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Maintenance)	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.
% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Induction)	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst)	Baseline to week 2, 4, 6, 8, 12

	with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions	
% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Maintenance).	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships,	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52

	treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions	
Median Time to Relapse (Weeks) From Week 12.	Median time to relapse (weeks) from week 12. Relapse is defined as greater than 50% loss of the maximal PASI improvement from baseline. PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical	Week 12 to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.

	signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement	
Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation;	Week 12

	scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into	Week 52

	Previous Biologic Psoriasis Therapy	4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s			

	previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Number of Visits With PASI 50, 75, 90, 100 Score and IGA Mod 2011 0 or 1	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50,	Week 16, 20, 24,28,32,36,40,44,48,and Week 52

	75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Number of Secukinumab Injections Needed to Regain PASI 75 Response From Start of Relapse After Week 12	The number of secukinumab injections needed for participants to regain PASI 75 response from the start of relapse after week 12	week 16, 20, 24,28,32,36,40,44,48,and Week 52
Number of Participants Developing Anti-secukinumab Antibodies	The development of anti-secunimubab anti-bodies will decrease a participant s ability to respond to secukinumab	Baseline, weeks 12, 24, 52 and 60

	treatment. The number of participants developing anti-secukinumab anti-bodies was measured from Baseline to week 12, 24, 52 and 8 weeks after treatment at week 60	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2011-07-12

First Submitted that Met QC Criteria
2011-07-29

First Posted (Estimated)
2011-08-01

Results Reporting Dates

Results First Submitted
2015-02-13

Results First Submitted that Met QC Criteria
2015-04-30

Results First Posted (Estimated)
2015-05-19

Study Record Updates

Last Update Submitted that met QC Criteria
2015-04-30

Last Update Posted (Estimated)
2015-05-19

Last Verified
2015-04

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis
plaque
inflammatory skin disease
scaly patches
AIN457
secukinumab
Moderate to Severe Plaque type Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies, Monoclonal

Study Documents

No study documents available

C n ca Tr a s gov return to the CTG homepage

Go to the c ass c webs te

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our fu d sc a mer (https //c n ca tr a s gov/about-s te/d sc a mer) for deta s

C n ca Tr a s gov s a webs te and on ne database of c n ca research stud es and nformat on about the r resu ts The Nat ona L brary of Med c ne (NLM) ma nta ns the webs te **The study sponsor or investigator submits information** about the r study to C n ca Tr a s gov and **is responsible for the safety, science, and accuracy** of any study they st

Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study-bas cs/ earn-about-stud es)

COMPLETED

Effectiveness and Safety of 3 Dosing Regimens of CP-690,550 to Placebo in Subjects With Moderate to Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT00678210

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2012-12-19

Study Details Tab

Study Overview

Brief Summary

The purpose of th s study s to determ ne the effect veness and safety, over 12 weeks, of 3 dos ng reg mens of CP-690,550 for the treatment of adu ts w th moderate to severe chron c p aque psor as s

Official Title

A Phase 2B, Mu t center, Random zed, Doub e-B nd, Para e -Group, P acebo-Contro ed Tr a Eva uat ng The Efficacy And Safety Of Dose Reg mens W th Ora CP-690,550 n The Treatment Of Subjects W th Moderate To Severe Chron c P aque Psor as s

Conditions

Psor as s

Intervention / Treatment

- Drug: CP-690,550
- Drug: CP-690,550
- Drug: CP-690,550

Feedback

- Drug: P acebo

Other Study ID Numbers

- A3921047

Study Start

2008-07

Primary Completion (Actual)

2009-08

Study Completion (Actual)

2009-08

Enrollment (Actual)

197

Study Type

ntervent ona

Phase

Phase 2

Resource links provided by the National Library of Medicine

Med neP us (https //med nep us gov/) re ated top cs Psor as s (https //med nep us gov/psor as s htm)

Genet c and Rare D seases nformat on Center (https //rared seases nfo n h gov/gard) resources
Chron c Graft Versus Host D sease (https //rared seases nfo n h gov/d seases/10964/chron c-graft-versus-host-d sease)

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

United States

Arizona Locations

Tucson, Arizona, United States, 85710
Pfizer nvest gat ona S te

Arkansas Locations

Little Rock, Arkansas, United States, 72205
Pfizer nvest gat ona S te

California Locations

C ck to v ew nteract ve map

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treatments

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study-bas cs/ earn-about-stud es)

Eligibility Criteria

Description

nc us on Cr ter a

- Have been d agnosed w th p aque psor as s for at east 6 months
- Have p aque psor as s cover ng at east 15% of the r tota body
- Be a cand date for phototherapy or system c treatment of psor as s (e ther naïve or h story of prev ous treatment)
- Be w ng and ab e to comp y w th schedu ed v s ts, treatment p an and other study procedures

Exc us on Cr ter a

- Current y have non-p aque forms of psor as s or drug- nduced psor as s
- Subject cannot d scont nue system c therap es and/or top ca therap es for the treatment of psor as s and cannot d scont nue phototherapy
- Subject s part c pat ng n another tr a us ng an nvest gat ona agent or procedure
- Women who are pregnant or breast-feed ng or cons der ng becom ng pregnant

Ages Eligible for Study

18 Years and o der (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Random zed
Interventional Model : Para e Ass gnment
Masking : Doub e (Part c pant, nvest gator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 1	Drug: CP-690,550 • tablets, 2 mg BID for 12 weeks
Experimental: 2	Drug: CP-690,550 • tablets, 5 mg BID for 12 weeks
Experimental: 3	Drug: CP-690,550 • tablets, 15 mg BID for 12 weeks
Placebo Comparator: 4	Drug: Placebo • tablets, BID for 12 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a 75% Improvement in Psoriasis Area and Severity Index (PASI 75) Score at Week 12	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%) - 6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters	Week 12

	for each section*area score*weighing factor(head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving Physician's Global Assessment (PGA) Score of Clear or Almost Clear	Physician global assessment of psoriasis is global consideration of the erythema, induration and scaling across all psoriatic lesions, rated separately over the whole body according to a 5-point severity scale ranged from 0 to 4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. The severity scores are summed and averaged after which the total average is rounded to the nearest whole number score to determine the treatment area overall severity of psoriasis score and category. The score of 0 clear, 1 almost clear, 2 mild, 3 moderate, 4 severe.	Week 2, 4, 8, 12, 14, 16
Percentage of Participants Achieving a 75% Improvement in Psoriasis Area and Severity Index (PASI 75) Score	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%) - 6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor(head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	Week 2, 4, 8, 14, 16
Percentage of Participants Achieving a 50% Improvement in Psoriasis Area and Severity Index (PASI 50) Score	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%) - 6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor(head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	Week 2, 4, 8, 12, 14, 16
Percentage of Participants Achieving a 90% Improvement in Psoriasis Area and Severity Index (PASI 90) Score	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%)-6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor (head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	Week 12

Psoriasis Area and Severity Index (PASI) Component Scores and Total Score	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%)-6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor (head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	Baseline, Week 2, 4, 8, 12, 14, 16
Change From Baseline in Psoriasis Area and Severity Index (PASI) Component Scores and Total Score at Week 2, 4, 8, 12, 14, and 16	Combined assessment of lesion severity and area affected into single score; range 0(no disease)-72(maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated:0(0%) - 6(90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor(head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4).	Baseline, Week 2, 4, 8, 12, 14, 16

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona L brary of Med c ne (NLM) to make sure they meet spec fic qua ty contro standards before be ng posted on the pub c webs te

Study Registration Dates

First Submitted
2008-05-13

First Submitted that Met QC Criteria
2008-05-13

First Posted (Estimated)
2008-05-15

Results Reporting Dates

Results First Submitted
2012-11-19

Results First Submitted that Met QC Criteria
2012-11-19

Results First Posted (Estimated)
2012-12-19

Study Record Updates

Last Update Submitted that met QC Criteria
2012-11-19

Last Update Posted (Estimated)
2012-12-19

Last Verified
2012-11

More Information

Terms related to this study

Keywords Provided by Pfizer

dose response; PAS 75 response endpo nt; subjects w th moderate to severe chron c p aque psor as s

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s
Janus K nase nh b tors
Prote n K nase nh b tors
Enzyme nh b tors

Mo ecu ar Mechan sms of Pharmaco og ca Act on
Tofac t n b

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=A3921047&StudyName=Effect veness%20and%20safety%20of%203%20dos ng%20reg mens%20of%20CP-690%2C550%20to%20p acebo%20 n%20sub ects%20w th%20moderate%20to%20severe%20chron c%20p aque%20psor as s)

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Record 1 of 1

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Read our fu d sc a mer (https //c n ca tr a s gov/about-s te/d sc a mer) for deta s

C n ca Tr a s gov s a webs te and on ne database of c n ca research stud es and nformat on about the r resu ts The Nat ona L brary of Med c ne (NLM) ma nta ns the webs te **The study sponsor or investigator submits information** about the r study to C n ca Tr a s gov and **is responsible for the safety, science, and accuracy** of any study they st

Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study-bas cs/ earn-about-stud es)

COMPLETED

Study Of The Mechanism Of Action Of CP-690,550 In The Skin Of Subjects With Moderate To Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT01710046

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2015-04-13

Study Details Tab

Study Overview

Brief Summary

There are ce s n the sk n and b ood of humans w th chron c moderate to severe p aque psor as s w th spec fic act v t es that may determ ne the effect veness of treatment These act v t es may be descr bed by obta n ng samp es of sk n and b ood and ana yz ng them us ng a var ety of tests

Detailed Description

The fina subject n Cohort 1 comp eted the study on 19-Nov-2013 (LSLV date) Because the study ana yses were nove and exp oratory, they requ red extens ve ana yses by study team and externa experts As a resu t of th s ana ys s t was determ ned on 21-Ju y-2014 that the data from Cohort 1 were suffic ent y defin t ve and that enro ment of Cohort 2 wou d not be just fied S nce th s dec s on resu ted n the LSLV for Cohort 1 becom ng the LSLV for the study, the fu data ana ys s and report ng s not projected to be comp ete w th n 12 Months of LSLV The fina ana ys s and fina report ng s p anned to be comp eted on 18-Feb-2015 Resu ts for th s data are ant c pated to be re eased n Apr 2015

Official Title

An Exp oratory Phase 2a, Random zed, Doub e-b nd, P acebo-contro ed, Mu t center Study To Assess Mechan sm Of Act on (Moa) Of Cp-690,550 n The Sk n When Adm n stered Ora y At 10 Mg Tw ce Da y (B d) For 12 Weeks n Subjects W th Moderate To Severe Chron c P aque Psor as s

Conditions

P aque Psor as s

Feedback

Intervention / Treatment

- Drug: (CP-6890,550) Tofac t n b
- Drug: P acebo
- Drug: (CP-690,550) Tofac t n b
- Drug: P acebo

Other Study ID Numbers

- A3921147

Study Start

2013-03

Primary Completion (Actual)

2013-11

Study Completion (Actual)

2013-11

Enrollment (Actual)

12

Study Type

ntervent ona

Phase

Phase 2

Resource links provided by the National Library of Medicine

Med neP us (https //med nep us gov/) re ated top cs Psor as s (https //med nep us gov/psor as s htm)

Genet c and Rare D seases nformat on Center (https //rared seases nfo n h gov/gard) resources
Chron c Graft Versus Host D sease (https //rared seases nfo n h gov/d seases/10964/chron c-graft-versus-host-d sease)

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

United States

California Locations

Los Angeles, California, United States, 90045
Dermato ogy Research Assoc ates

Florida Locations

Tampa, Florida, United States, 33609

C ck to v ew nteract ve map

O ymp an C n ca Research

Texas Locations

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treatments

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study-bas cs/ earn-about-stud es)

Eligibility Criteria

Description

nc us on Cr ter a

- Adu ts over 18 years of age w th a d agnos s of chron c moderate to severe p aque psor as s for at east 12 months; n genera y good hea th; on stab e dose of non-proh b ted med cat ons; ab e to stop current psor as s therapy (system c or top ca) for severa weeks pr or to and dur ng study part c pat on

Exc us on Cr ter a

- Ser ous under y ng d sease nc ud ng v ra d sorders such as hepat t s or H V or sk n cond t on that wou d nterfere w th sk n b ops es or eva uat on of psor as s; cond t ons that cou d nterfere w th drug absorpt on after ora adm n strat on; h story of ma gnancy or auto- mmune d sease
- Use of ora or njected cort costero ds (stero ds)

Ages Eligible for Study

18 Years and o der (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Random zed
Interventional Model : Para e Ass gnment
Masking : Tr p e (Part c pant, nvest gator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Cohort 1	Drug: (CP-6890,550) Tofacitinib • 2 x 5 mg oral capsules taken twice daily (every 12 hours) for 12 consecutive weeks Drug: Placebo • 2 matching oral capsules taken twice daily (every 12 hours) for 12 consecutive weeks
Experimental: Cohort 2	Drug: (CP-690,550) Tofacitinib • 2 x 5 mg oral capsules taken twice daily (every 12 hours) for 12 weeks Drug: Placebo • 2 matching oral capsules taken twice daily (every 12 hours) for 12 consecutive weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a 75% Reduction in the Psoriasis Area and Severity Index (PASI75) at Week 12	Combined assessment of lesion severity and area affected into single score; range equals ( ) 0 (no disease) to 72 (maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated: 0 (0%) to 6 (90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor (head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4) summed over all sections.	Week 12
Percentage of Participants Achieving a Physician's Global Assessment (PGA) Response of Clear or Almost Clear at Week 12	PGA psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration and scaling across all psoriatic lesions. PGA of Psoriasis scale ranges from 0 (no psoriasis) to 4 (severe disease). â€˜Clearâ€™ and â€œAlmost clearâ€™ includes all participants who were scored as a 0 or 1.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Psoriasis Area and Severity Index (PASI) Score by Visit	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0 0% to 6 90â€ 100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0 none to 4 maximum. Final PASI sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4) summed over all sections; total possible score range: 0 no disease to 72 maximal disease.	Baseline and Weeks 1, 2, 4, and 12
Change From Baseline in PASI by Visit	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0 0% to 6 90â€ 100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0 none to 4 maximum. Final PASI sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4) summed over all sections; total possible score range: 0 no disease to 72 maximal disease.	Weeks 1, 2, 4 and 12
Percent Change From Baseline in PASI by Visit	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0 0% to 6 90â€ 100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0 none to 4 maximum. Final PASI sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4) summed over all sections; total possible score range: 0 no disease to 72 maximal disease.	Weeks 1, 2, 4, and 12
Percentage of Participants Achieving a PASI75 Response at Weeks 1, 2, and 4	Combined assessment of lesion severity and area affected into single score; range 0 (no disease) to 72 (maximal disease). Body divided into 4 sections head, upper/lower limbs, trunk; each area scored by itself and scores combined for final PASI. For each section percent area of skin involved was estimated: 0 (0%) to 6 (90-100%) and severity estimated by clinical signs of erythema, induration, scaling; ranged 0-4: 0 none, 1 slight, 2 moderate, 3 marked, 4 very marked. Final PASI sum of severity parameters for each section*area score*weighing factor (head 0.1, upper limbs 0.2, trunk 0.3, lower limbs 0.4) summed over all sections.	Weeks 1, 2, and 4
Change From Baseline in PGA Score by Visit	PGA psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. PGA of Psoriasis scale ranges from 0 (no psoriasis) to 4 (severe disease). The severity scores of 3 components (erythema, induration, and scaling) are averaged and rounded to the nearest whole number to determine the PGA score.	Weeks 1, 2, 4, and 12
Percentage of Participants in Each PGA Category at		Baseline and Weeks 1, 2, 4, and 12

Various Timepoints by Baseline Category		
Percentage of Participants by PGA Response Category and Timepoint	PGA psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration and scaling across all psoriatic lesions. PGA of Psoriasis scale ranges from 0 (no psoriasis) to 4 (severe disease). Response category scores: 0 clear; 1 almost clear; 2 mild; 3 moderate; and 4 severe. The severity scores of 3 components (erythema, induration, and scaling) are averaged and rounded to the nearest whole number to determine the PGA score.	Baseline and Weeks 1, 2, 4, and 12
Body Surface Area (BSA)	Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (ie, the participant's fully extended palm, fingers and thumb together) represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. In each body region, the percent body region surface area with psoriasis is multiplied by the Body Region Weighting (head and neck 10%, upper limbs 5%, trunk including axillae and groin] 3.33% and lower limbs including buttocks] 2.5%). BSA (%) 0.1Sh + 0.2Sh+0.3St+0.4Sl, where S body region suface area with psoriasis: h head; u upper limbs; t trunk; l lower limbs.	Baseline and Weeks 1, 2, 4, and 12
Change From Baseline in BSA	Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (ie, the participant's fully extended palm, fingers and thumb together) represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. In each body region, the percent body region surface area with psoriasis is multiplied by the Body Region Weighting (head and neck 10%, upper limbs 5%, trunk including axillae and groin] 3.33% and lower limbs including buttocks] 2.5%). BSA (%) 0.1Sh + 0.2Sh+0.3St+0.4Sl, where S body region suface area with psoriasis: h head; u upper limbs; t trunk; l lower limbs.	Weeks 1, 2, 4, and 12
Percent Change From Baseline in BSA	Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (ie, the participant's fully extended palm, fingers and thumb together) represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. In each body	Weeks 1, 2, 4, and 12

	region, the percent body region surface area with psoriasis is multiplied by the Body Region Weighting (head and neck 10%, upper limbs 5%, trunk including axillae and groin] 3.33% and lower limbs including buttocks] 2.5%). BSA (%) 0.1Sh + 0.2Sh+0.3St+0.4Sl, where S body region suface area with psoriasis: h head; u upper limbs; t trunk; l lower limbs.	
Itch Severity Item (ISI) Score by Visit	The severity of itch (pruritus) due to psoriasis was assessed using the ISI, a single-item, horizontal numeric rating scale. Participants were asked to rate your worst itching due to psoriasis over the past 24 hours on a numeric rating scale anchored by the terms No itching (0) and Worst possible itching (10) at the ends. the baseline is defined as the average of all available diary entries before Baseline/Day 1 and the in-clinic measurement on Baseline/day 1. Week 1 is the mean of daily values of study days 2 to 8 and Week 2 is the mean of daily values of study days 9 to 15.	Baseline and Weeks 1, 2, 4, and 12
Change From Baseline in ISI by Visit	ISI, a single-item, horizontal numeric rating scale. Participants were asked to rate your worst itching due to psoriasis over the past 24 hours on a numeric rating scale anchored by the terms No itching (0) and Worst possible itching (10) at the ends. The baseline is defined as the average of all available diary entries before Baseline/Day 1 and the in-clinic measurement on Baseline/Day 1. Week 1 is the mean of daily values of study days 2 to 8 and Week 2 is the mean of daily values of study days 9 to 15. A negative value indicates an improvement.	Weeks 1, 2, 4 and 12
Target Plaque Severity Score (TPSS) by Visit	Target lesions were selected at baseline and followed for the duration of the study. Each target lesion was scored by the investigator on severity of erythema, induration, and scaling according to a 5-point (0 to 4) severity scale with a maximum sum score for a plaque of 12. The TPSS was calculated as the sum of the scores for erythema, induration, and scaling; the score can vary in increments of 1 unit from 0 to 12.	Baseline and Weeks 1, 2, 4, and 12
Percent Change From Baseline in TPSS by Visit	Target lesions were selected at baseline and followed for the duration of the study. Each target lesion was scored by the investigator on severity of erythema, induration, and scaling according to a 5-point (0 to 4) severity scale with a maximum sum score for a plaque of 12. The TPSS was calculated as the sum of the scores for erythema, induration, and scaling; the score can vary in increments of 1 unit from 0 to 12. A negative value indicated improvment.	Weeks 1, 2, 4, and 12

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona L brary of Med c ne (NLM) to make sure they meet spec fic qua ty contro standards before be ng posted on the pub c webs te

Study Registration Dates

First Submitted
2012-10-16

First Submitted that Met QC Criteria
2012-10-16

First Posted (Estimated)
2012-10-18

Results Reporting Dates

Results First Submitted
2015-03-30

Results First Submitted that Met QC Criteria
2015-03-30

Results First Posted (Estimated)
2015-04-13

Study Record Updates

Last Update Submitted that met QC Criteria
2015-03-30

Last Update Posted (Estimated)
2015-04-13

Last Verified
2015-03

More Information

Terms related to this study

Keywords Provided by Pfizer

p aque psor as s
tofac t n b
b opsy
Janus K nase
random zed p acebo contro ed c n ca tr a
psor as s vu gar s

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s
Janus K nase nh b tors
Prote n K nase nh b tors
Enzyme nh b tors
Mo ecu ar Mechan sms of Pharmaco og ca Act on
Tofac t n b

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=A3921147&StudyName=Study%20Of%20The%20Mechan sm%20Of%20Act on%20Of%20CP-690%2C550%20 n%20The%20Sk n%20Of%20Sub ects%20W th%20Moderate%20To%20Severe%20Chron c%20P aque%20Psor as s)

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

Withdrawal of marketing autorization of efalizumab by the EMEA.

Effect of Topical Calcipotriene/Betamethasone (Taclonex) in Managing Localized Breakthrough in Moderate to Severe Plaque Psoriasis in Patients Receiving Efalizumab (Raptiva)

ClinicalTrials.gov ID NCT00608777

Sponsor Derm Research, PLLC

Information provided by Leon Kircik, M.D., Derm Research, PLLC (Responsible Party)

Last Update Posted 2012 08 10

Study Details Tab

Feedback

Study Overview

Brief Summary

The purpose of this study is to determine if calcipotriene/bethamethasone can safely and effectively manage the occurence of LMB (mild localized breakthrough) in patients recieving efalizumab (Raptiva) for moderate to severe plaque psoriasis.

It is hypothesized that calcipotriene/betamethasone (Taclonex) could be used to manage LMB and thus allow patients to continue efalizumab without interruption.

Detailed Description

LMB (localized mild breakthrough)is one of two psoriasis adverse events commonly seen in efalizumab treated patients. It is generally papular in nature and does not involve existing lesions. Clinical experience suggests that LMB may not have a clinical impact in patients responding to efalizumab and therefore may be treated without interrupting efalizumab therapy. To relieve discomfort topical therapy may be indicated until the symptoms are resolved.

This is a single arm, open label study. Fifteen patients who are receiving efalizumab before entrance into this study and who develop LMB wil be enrolled. Topical calcipotriene/betamethasone (Taclonex) will be applied to the areas (except face, axillae or groin) once a day for two weeks. The PI may choose to continue two more weeks if needed for a total of four weeks of therapy. All patients will continue with efalizumab without dose modification for the duration of the study. Patients will return for follow up visits at weeks 2, 4 and 6. Topical desonide may be used for LMB involvement of the face, groin or axillae.

Official Title

Effect of Topical Calcipotriene/Betamethasone (Taclonex) in Managing Localized Mild Breakthrough in Moderate to Severe Plaque Psoriasis Patients Receiving Efalizumab (Raptiva).

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Calcipotriene/betamethasone

Other Study ID Numbers

- ACD4311s

Study Start

2008 01

Primary Completion (Actual)

2009 02

Study Completion (Actual)

2009 02

Enrollment (Actual)

6

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Betamethasone (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Betamethasone) Calcipotriene (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Calcipotriene) Daivobet (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Daivobet)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Kentucky Locations

Louisville, Kentucky, United States, 40217
DermResearch, PLLC

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Ability to provide written, informed consent and comply with study assessments for the full duration of the study.
- Age 18 years or older.
- Moderate to severe plaque psoriasis being treated with efalizumab.
- Develop LMB during efalizumab treatment.
- PGA of LMB at least mild (2) excluding face, axillae and groin.

Exclusion Criteria:

- Patients with known hypersensitivity to efalizumab, calcipotriene/betamethasone or any of its components.
- Pregnant or lactating women.
- Known or suspected disorders of calcium metabolism.
- Erythrodermic, exfoliative and/or pustular psoriasis.
- Concomitant use of topical thaerapy, phototherapy or immunosuppressive agents.
- LMB (in areas other than face, axillae or groin) constitutes more than 30% of total body surface area.
- Patients with generalized inflammatory flare which is defined as widespread worsening of psoriasis characterized by erythematous and and edematous lesions within exisiting plaques.
- Any other condition the investigator believes would pose a significant hazard to the subject if the investigational therapy were initiated.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Intervention/Treatment
Drug: Calcipotriene/betamethasone • One application to affected areas, once a day for two weeks. The PI may choose to extend treatment until Week 4 if necessary. • Other Names: ◦ Taclonex

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Proportion of Subjects Who Acheive a Score of Clear (0) or Almost Clear (1) on the PGA of LMB at Week 2		week 2

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Derm Research, PLLC

Collaborators

- Genentech, Inc.

Investigators

- Principal Investigator: Leon H Kircik, M.D., DermResearch, PLLC

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- de Jong EM. The course of psoriasis. Clin Dermatol. 1997 Sep Oct;15(5):687 92. doi: 10.1016/s0738 081x(97)00023 0. No abstract available. (https://pubmed.ncbi.nlm.nih.gov/9313967)
- Carey W, Glazer S, Gottlieb AB, Lebwohl M, Leonardi C, Menter A, Papp K, Rundle AC, Toth D. Relapse, rebound, and psoriasis adverse events: an advisory group report. J Am Acad Dermatol. 2006 Apr;54(4 Suppl 1):S171 81. doi: 10.1016/j.jaad.2005.10.029. (https://pubmed.ncbi.nlm.nih.gov/16488339)
- Menter A, Leonardi CL, Sterry W, Bos JD, Papp KA. Long term management of plaque psoriasis with continuous efalizumab therapy. J Am Acad Dermatol. 2006 Apr;54(4 Suppl 1):S182 8. doi: 10.1016/j.jaad.2005.10.028. No abstract available. (https://pubmed.ncbi.nlm.nih.gov/16488340)
- Werther WA, Gonzalez TN, O Connor SJ, McCabe S, Chan B, Hotaling T, Champe M, Fox JA, Jardieu PM, Berman PW, Presta LG. Humanization of an anti lymphocyte function associated antigen (LFA) 1 monoclonal antibody and reengineering of the humanized antibody for binding to rhesus LFA 1. J Immunol. 1996 Dec 1;157(11):4986 95. (https://pubmed.ncbi.nlm.nih.gov/8943405)
- Raptiva Prescribing Information. Genentech, Inc. June 2005
- Taclonex Prescribing Information. Warner Chilcott (US), Inc. Jan 2006

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2008-01-23

First Submitted that Met QC Criteria
2008-01-23

First Posted (Estimated)
2008-02-06

Results Reporting Dates

Results First Submitted
2012-03-05

Results First Submitted that Met QC Criteria
2012-03-05

Results First Posted (Estimated)
2012-04-03

Study Record Updates

Last Update Submitted that met QC Criteria
2012-08-07

Last Update Posted (Estimated)
2012-08-10

Last Verified
2012-08

More Information

Terms related to this study

Keywords Provided by Leon Kircik, M.D., Derm Research, PLLC

Localized mild breakthrough

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents

Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Anti Asthmatic Agents
Respiratory System Agents
Dermatologic Agents
Betamethasone
Calcipotriene

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Efficacy and Safety of Namilumab (MT203) for Plaque Psoriasis

ClinicalTrials.gov ID **NCT02129777**

Sponsor Takeda

Information provided by Takeda (Responsible Party)

Last Update Posted 2017 04 07

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to establish proof of efficacy for namilumab in moderate to severe plaque psoriasis, measured as Psoriasis Area and Severity Index (PASI)75 response rate at Week 12.

Feedback

Detailed Description

The drug tested in this study is called namilumab. Namilumab was tested to prove its effectiveness in treating moderate to severe chronic plaque psoriasis. This study looked at improvement of plaque psoriasis in participants who take namilumab.

The study enrolled 122 participants. Participants were randomly assigned (by chance, like flipping a coin) to one of five treatment groups that were undisclosed to the patient and study doctor during the study (unless there was an urgent medical need):

- Namilumab subcutaneous injection 300 mg Day 1, 150 mg Days 15, 43 and 71
- Namilumab subcutaneous injection 160 mg Day 1, 80 mg Days 15, 43 and 71
- Namilumab subcutaneous injection 100 mg Day 1, 50 mg Days 15, 43 and 71
- Namilumab subcutaneous injection 40 mg Day 1, 20 mg Days 15, 43 and 71
- Placebo (dummy inactive subcutaneous injection) this is a liquid solution that looks like the study drug but has no active ingredient Days 1, 15, 43 and 71.

This study consisted of two parts. Eligible participants received 10 weeks of treatment with double blinded study medication, followed by an extended treatment period (active extension period, intended to be 52 weeks) with open label study medication. At Week 12, participants were assessed for primary endpoint response, which determined the course of their progression through the open label treatment period. Participants who showed >=75% reduction of Baseline (Day 1) PASI at Week 12, "Responders", began a washout interval (for a maximum of 24 weeks) with no use of study medication: this interval continued until a partial (25%) loss of Week 12 treatment response is recorded in assessments conducted on a 2 weekly basis thereby prompting the start of dosing with open label (OL) study medication (Day 0 OL through Week 52 OL). In contrast, participants who did not show >=75% reduction of Baseline PASI score at Week 12, "Partial/Non Responders", began the open label extension period 4 weeks after the final dose of blinded study medication.

Participants were then followed up through an 18 week post treatment assessment period during which no medication was given. During the open label extension period participants began dosing with 80 mg namilumab; however, if an inadequate treatment response was recorded, then dose escalation to 150 mg namilumab was implemented.

Official Title

A Multi Centre, Randomized, Double Blind, Placebo Controlled, Dose Finding and Proof of Concept Study, to Assess the Efficacy, Safety and Tolerability, Pharmacokinetics and Pharmacodynamics of Namilumab/MT203 at 4 Different Subcutaneous Doses Together With an Open Label, Dose Escalated Extension to Assess Safety and Efficacy of One Year Treatment in Subjects With Moderate to Severe Chronic Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Namilumab

- Drug: Placebo

Other Study ID Numbers

- M1 1188_203
- U1111 1146 1219 (Other Identifier) (OTHER: WHO)
- 2013 002806 30 (EudraCT Number)
- 172235 (Registry Identifier) (REGISTRY: HC CTD)

Study Start

2014 06

Primary Completion (Actual)

2015 09

Study Completion (Actual)

2016 02

Enrollment (Actual)

122

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Canada

Quebec, Canada

Alberta Locations

Calgary, Alberta, Canada

Edmonton, Alberta, Canada

Ontario Locations

Barrie, Ontario, Canada

Hamilton, Ontario, Canada



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Is male or female aged 18 to 70 years, inclusive.
2. Is suffering from active but clinically stable plaque psoriasis (for at least 6 months) involving >=10% of their body surface area and Psoriasis Area and Severity Index (PASI) score >=12.
3. Must have been a candidate for, or have received, >= phototherapy or systemic psoriasis therapy.
4. A male participant who is non sterilized and sexually active with a female partner of childbearing potential agrees to use adequate contraception from signing of the informed consent throughout the duration of the study (including the treatment period and 18 weeks after last dose of study medication).
5. A female participant of childbearing potential who is sexually active with a non sterilized male partner agrees to routinely use adequate contraception from signing of the informed consent throughout the duration of the study (including the treatment period and 18 weeks after last dose of study medication).
6. In the opinion of the investigator, is capable of understanding and complying with protocol requirements.
7. The participant or, when applicable, the participant s legally acceptable representative signs and dates a written informed consent form and any required privacy authorization prior to the initiation of any study procedures.

Exclusion Criteria:

1. Has received any investigational agent during an interval equivalent to 5 half lives for that agent agent or an interval of 30 days if longer prior to the study Baseline clinic visit, or is participating / plans to participate in any other clinical trial during this study.
2. Has received namilumab, any other Granulocyte Macrophage Colony Stimulating Factor (GM CSF) / GM CSF receptor or granulocyte stimulating factor (G GSF) signaling inhibitor either in a previous clinical study or as a therapeutic agent.
3. Is required to take excluded medications.
4. Has a history of hypersensitivity or allergies to namilumab or any of the contents of the formulation.
5. Has other forms of psoriasis (eg drug induced psoriasis, pustular, erythrodermic, exfoliative, inverse and/or guttate psoriasis).
6. Evidence of skin conditions other than psoriasis (eg, eczema) at the time of the Screening clinic visit, or between the Screening visit and study drug initiation, that would interfere with evaluations of the effect of investigational product on psoriasis.
7. Has a history or evidence of a clinically significant disorder (including but not limited to cardiopulmonary, oncologic, renal, metabolic, hematologic or psychiatric), condition or disease that, in the opinion of the investigator and Takeda physician would pose a risk to participant safety or interfere with the study evaluation, procedures or completion.
8. Evidence of clinically uncontrolled respiratory disease (including sarcoidosis) on the basis of data from the subjects respiratory assessments including chest X ray, lung

function tests (forced expiratory volume in one second [FEV1], forced vital capacity [FVC], peak expiratory flow rate [PEFR]) and pulse oximetry performed at Screening. The subjects must have saturation of peripheral oxygen (SpO2) ≥ 94%, FEV1 and/or FVC ≥ 60 % of predicted values at Screening and Baseline and no uncontrolled lung disease. Subject treatment initiated or modified to control lung disease within 24 weeks prior to Screening must be considered exclusionary.

9. History of clinically significant interstitial lung disease e.g. chronic or recurrent pulmonary infection where macrophages are important for the clearance of the infection (such as Pneumocystis (carinii) jiroveci pneumonia, allergic bronchopulmonary aspergillosis, Nocardia infections, Actinomyces infection).
10. Presence or history of active tuberculosis (TB) or latent TB infection, where no anti TB treatment has been given or where successful completion of an appropriate course of anti TB therapy cannot be documented.
11. A positive QuantiFERON TB Gold test and / or evidence of active or latent TB by chest X ray, not accompanied by initiation of an approved regimen of anti TB therapy at least 12 months prior to the Baseline clinic visit.
12. Has a history of severe chronic obstructive pulmonary disease (COPD) and / or history of severe COPD exacerbation(s), or a history of asthma with exacerbations requiring hospitalization, within the last 12 months prior to the Screening visit.
13. History of methotrexate treatment associated lung toxicity.
14. Has a history of cancer within the last 10 years except for adequately managed basal cell or squamous cell carcinoma of the skin or in situ carcinoma of the cervix treated and considered cured.
15. Has a history of treatment with anti cancer chemotherapy (e.g. alkylating agents, anti metabolites, purine analogues) and/or monoclonal antibodies, or has received GM CSF / G CSF treatment associated with chemotherapy within the last 5 years.
16. Has an underlying condition that predisposes to infections (eg immunodeficiency, history of poorly controlled diabetes, splenectomy).
17. Has any clinically significant illness within 4 weeks prior to the first dose of study medication or during the study including acute or chronic infectious disease, which may influence the outcome of the study.
18. Has a known history of infection with hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV), or has serological findings at the Screening visit which indicate active or latent hepatitis B, hepatitis C or HIV infection.
19. Has, in the judgment of the investigator, clinically significant abnormal clinical laboratory parameters at Screening including, but not limited to: Hemoglobin <8.5 g/dL, Neutrophils <1500/mm^3, Platelet count <75 000 cells/mm^3 and AST or ALT >2 x ULN.
20. Has a history of drug abuse (defined as any illicit drug use), or a history of alcohol abuse within 2 years prior to the Screening visit.
21. Any other condition that, in the judgment of the investigator, might cause this study to be detrimental to the participant s health.
22. If female, is (a) pregnant / lactating / intending to become pregnant before or within the period of 18 weeks immediately after receiving the last dose of study medication; (b) intending to donate ova during this time period.
23. Intends to donate sperm during the course of this study or within a period of 18 weeks after receiving the last dose of study medication.

24. Is an immediate family member, study site employee, or is in a dependent relationship with a study site employee involved in conduct of this study (eg, spouse, parent, child, sibling), or may consent under duress.

Ages Eligible for Study

18 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Blinded period: Namilumab 300 mg + namilumab 150 mg Namilumab 300 mg (2 separate injections of 150 mg), subcutaneous injection, on Day 1, followed by namilumab 150 mg subcutaneous injection, on Days 15, 43 and 71.	Drug: Namilumab • Namilumab subcutaneous injection • Other Names: ◦ MT203
Experimental: Blinded period: Namilumab 160 mg + namilumab 80 mg Namilumab 160 mg (2 separate injections of 80 mg), subcutaneous injection, on Day 1, followed by namilumab 80 mg subcutaneous injection, on Days 15, 43 and 71.	Drug: Namilumab • Namilumab subcutaneous injection • Other Names: ◦ MT203
Experimental: Blinded period: Namilumab 100 mg + namilumab 50 mg	Drug: Namilumab • Namilumab subcutaneous injection • Other Names:

Namilumab 100 mg (2 separate injections of 50 mg), subcutaneous injection, on Day 1, followed by namilumab 50 mg subcutaneous injection, on Days 15, 43 and 71.	◦ MT203
Experimental: Blinded period: Namilumab 40 mg + namilumab 20 mg Namilumab 40 mg (2 separate injections of 20 mg), subcutaneous injection, on Day 1, followed by namilumab 20 mg subcutaneous injection, on Days 15, 43 and 71.	Drug: Namilumab • Namilumab subcutaneous injection • Other Names: ◦ MT203
Placebo Comparator: Blinded period: Placebo Placebo (2 separate injections), subcutaneous injection, on Day 1, followed by placebo, subcutaneous injection, on Days 15, 43 and 71.	Drug: Placebo • Placebo subcutaneous injection
Experimental: Open label: Namilumab 80 mg	Drug: Namilumab • Namilumab subcutaneous injection

Namilumab 80 mg subcutaneous injection, at Week 0 and every 4 weeks thereafter up to 52 weeks (active extension period) - if appropriate on the basis of treatment response.	• Other Names: ◦ MT203
Experimental: Open label: Namilumab 150 mg Namilumab 150 mg, subcutaneous injection, from Week 8 and then every 4 weeks thereafter up to 52 weeks (active extension period) - if appropriate on the basis of treatment response.	Drug: Namilumab • Namilumab subcutaneous injection • Other Names: ◦ MT203

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving 75 Percent Reduction From Baseline Psoriasis Area	PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. The body was divided into 4 sections: head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent body surface area (A) involved was estimated: 0= No involvement to 6= 90-100 percent (%). Severity	Week 12

and Severity Index (PASI) Score (PASI75 Response) at Week 12	was estimated by clinical signs: erythema (E), induration (I), and desquamation (D); scale: 0= no symptoms to 4= very marked. Final PASI = 0.1(Eh + Ih + Dh)Ah + 0.3(Et + It + Dt)At + 0.2(Eu + Iu + Du)Au + 0.4(El + Il + Dl)Al where head: 0.1, upper extremities (arms): 0.2, trunk: 0.3, lower extremities (legs): 0.4 (corresponding to approximately 10%, 20%, 30%, and 40% of body surface area, respectively); total possible score range: 0= no disease to 72= maximal disease. Participants showing at least 75% reduction in PASI score relative to baseline PASI Score are reported.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving 75 Percent Reduction From Baseline PASI Score (PASI75 Response) at Weeks 2, 4, 6, and 10	PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. The body was divided into 4 sections: head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent body surface area (A) involved was estimated: 0= No involvement to 6= 90-100 percent (%). Severity was estimated by clinical signs: erythema (E), induration (I), and desquamation (D); scale: 0= no symptoms to 4= very marked. Final PASI = 0.1(Eh + Ih + Dh)Ah + 0.3(Et + It + Dt)At + 0.2(Eu + Iu + Du)Au + 0.4(El + Il + Dl)Al where head: 0.1, upper extremities (arms): 0.2, trunk: 0.3, lower extremities (legs): 0.4 (corresponding to approximately 10%, 20%, 30%, and 40% of body surface area, respectively); total possible score range: 0= no disease to 72= maximal disease. Participants showing at least 75% reduction in PASI score relative to baseline PASI Score are reported.	Weeks 2, 4, 6 and 10

Change From Baseline in PASI Score at Weeks 2, 4, 6, 10, and 12	PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. The body was divided into 4 sections: head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent body surface area (A) involved was estimated: 0= No involvement to 6= 90-100 percent (%). Severity was estimated by clinical signs: erythema (E), induration (I), and desquamation (D); scale: 0= no symptoms to 4= very marked. Final PASI = 0.1(Eh + Ih + Dh)Ah + 0.3(Et + It + Dt)At + 0.2(Eu + Iu + Du)Au + 0.4(El + Il + Dl)Al where head: 0.1, upper extremities (arms): 0.2, trunk: 0.3, lower extremities (legs): 0.4 (corresponding to approximately 10%, 20%, 30%, and 40% of body surface area, respectively); total possible score range: 0= no disease to 72= maximal disease.	Baseline, Weeks 2, 4, 6, 10, and 12
Percentage of Participants Achieving 50 Percent Reduction From Baseline PASI Score (PASI50 Response) at Weeks 2, 4, 6, 10 and 12	PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. The body was divided into 4 sections: head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent body surface area (A) involved was estimated: 0= No involvement to 6= 90-100 percent (%). Severity was estimated by clinical signs: erythema (E), induration (I), and desquamation (D); scale: 0= no symptoms to 4= very marked. Final PASI = 0.1(Eh + Ih + Dh)Ah + 0.3(Et + It + Dt)At + 0.2(Eu + Iu + Du)Au + 0.4(El + Il + Dl)Al where head: 0.1, upper extremities (arms): 0.2, trunk: 0.3, lower extremities (legs): 0.4 (corresponding to approximately 10%, 20%, 30%, and 40% of body surface area, respectively); total possible score range: 0= no disease to 72= maximal disease. Participants showing at least 50% reduction in PASI score relative to baseline PASI Score are reported.	Weeks 2, 4, 6, 10 and 12

Percentage of Participants Achieving 90 Percent Reduction From Baseline PASI Score (PASI90 Response) at Weeks 2, 4, 6, 10 and 12	PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. The body was divided into 4 sections: head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent body surface area (A) involved was estimated: 0= No involvement to 6= 90-100 percent (%). Severity was estimated by clinical signs: erythema (E), induration (I), and desquamation (D); scale: 0= no symptoms to 4= very marked. Final PASI = 0.1(Eh + Ih + Dh)Ah + 0.3(Et + It + Dt)At + 0.2(Eu + Iu + Du)Au + 0.4(El + Il + Dl)Al where head: 0.1, upper extremities (arms): 0.2, trunk: 0.3, lower extremities (legs): 0.4 (corresponding to approximately 10%, 20%, 30%, and 40% of body surface area, respectively); total possible score range: 0= no disease to 72= maximal disease. Participants showing at least 90% reduction in PASI score relative to baseline PASI Score are reported.	Weeks 2, 4, 6, 10 and 12
Percentage of Participants Achieving Greater Than or Equal to (>=) 2 Point Improvement From Baseline in Static Physicians Global Assessment (sPGA) Score at Weeks 2, 4, 6, 10 and 12	sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe). Participants who had >=2 point improvement are reported.	Weeks 2, 4, 6, 10 and 12

Percentage of Participants Achieving a sPGA Response of Clear (0) or Almost Clear (1) at Weeks 2, 4, 6, 10 and 12	sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe). Clear and Almost clear included all participants who had scored a 0 or 1.	Weeks 2, 4, 6, 10 and 12
Change From Baseline in sPGA Score at Weeks 2, 4, 6, 10, and 12	sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe).	Baseline, Weeks 2, 4, 6, 10, and 12
Change From Baseline in Affected Body Surface Area (BSA) at Weeks 2, 4, 6, 10, and 12	Assessment of BSA with psoriasis was performed by means of the palm method, where the palm of the participant s hand represented 1% of BSA. The affected areas were then calculated by their size compared to the participant s palm.	Baseline, Weeks 2, 4, 6, 10, and 12
Change From Baseline in Visual Analogue Scale (VAS) Itching Score at Weeks 2, 4, 6, 10, and 12	Assessments were performed using a portable electronic device, which was kept and used by the participant throughout the duration of the study. Participants were asked to indicate their level of itching by marking a horizontal line with "No itch" at the left extreme and "Worst itch imaginable" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of itching experienced during the previous 24 hours.	Baseline, Weeks 2, 4, 6, 10, and 12
Change From Baseline in VAS Joint Pain Score	Assessments were performed using a portable electronic device, which was kept and used by the participant throughout the duration of the study. Participants were asked to indicate their	Baseline, Weeks 2, 4, 6, 10, and 12

at Weeks 2, 4, 6, 10, and 12	severity of joint pain by marking a horizontal line with "No pain" at the left extreme and "Worst pain imaginable" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of pain experienced during the previous 24 hours.	
Change From Baseline in VAS Morning Stiffness Score at Weeks 2, 4, 6, 10, and 12	Assessments were performed using a portable electronic device, which was kept and used by the participant throughout the duration of the study. Participants were asked to indicate their level of morning stiffness by marking a horizontal line with "No stiffness" at the left extreme and "Very severe stiffness" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of stiffness experienced by the participant since waking on that particular day.	Baseline, Weeks 2, 4, 6, 10, and 12
Change From Baseline in Duration of Morning Stiffness at Weeks 2, 4, 6, 10, and 12	Assessments were performed using a portable electronic device, which was kept and used by the participant throughout the duration of the study. Duration of stiffness was elicited in response to a standard question included in the portable device.	Baseline, Weeks 2, 4, 6, 10, and 12
Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 12	The DLQI is a 10-point rating scale for determining the impact of dermatological conditions on the participant s quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). Maximum total score is 30, where 0-1 represents "No effect at all on participant s life" and 21-30 "Extremely large effect on participant s life" - higher scores indicating poorer quality of life.	Baseline, Week 12

Change From Baseline in Short Form 36 Health Survey (SF-36) at Week 12	SF-36 is a standardized survey evaluating 8 aspects of functional health and well-being: physical and social functioning, physical and emotional role limitations, bodily pain, general health, vitality, mental health. These 8 aspects are summarized as physical and mental health summary scores. The score range for the physical and mental health scores is 0-100 (100=highest level of functioning).	Baseline, Week 12
Change From Baseline in EuroQoL Health Questionnaire (EQ-5D)- Index Score at Week 12	EQ-5D-Index score is a generic, multidimensional, health-related, quality-of-life instrument. The profile allows participants to rate their health state in 5 health domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The score ranges from -0.594 to 1.000. The higher score indicates a better health state perceived by the participant.	Baseline, Week 12
Change From Baseline in EQ-5D-VAS Score at Week 12	EQ-5D-VAS is a participant rated questionnaire to assess health-related quality of life in terms of a single index value. The VAS component rates current health state on a scale from 0 mm ("Worst imaginable health state") to 100 mm ("Best imaginable health state"); higher scores indicate a better health state.	Baseline, Week 12
Mean Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score at Weeks 2, 4, 6, 10, and 12	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lunula, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI	Baseline, Weeks 2, 4, 6, 10, and 12

	score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis.	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Takeda

Collaborators

No information provided

Investigators

- Study Director: Medical Director, Clinical Science, Takeda

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2014-04-14

First Submitted that Met QC Criteria
2014-04-30

First Posted (Estimated)
2014-05-02

Results Reporting Dates

Results First Submitted
2017-02-23

Results First Submitted that Met QC Criteria
2017-02-23

Results First Posted
2017-04-07

Study Record Updates

Last Update Submitted that met QC Criteria
2017-02-23

Last Update Posted
2017-04-07

Last Verified
2017-02

More Information

Terms related to this study

Keywords Provided by Takeda

Drug therapy

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous

Skin Diseases

Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Long-Term One Year Use of Alefacept (Amevive®) in Moderate to Severe Chronic Plaque Type Psoriasis

ClinicalTrials.gov ID NCT00655564

Sponsor Wake Forest University

Information provided by Wake Forest University Health Sciences (Wake Forest University) (Responsible Party)

Last Update Posted 2018 09 11

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this research study is to see how well the medication Alefacept (Amevive®) works for continuous treatment of chronic plaque psoriasis. The US Food and Drug Administration (FDA) has approved Alefacept in an intermittent dosage schedule of 15 mg weekly injection for 12 weeks followed by 12 weeks off treatment.

Detailed Description

To estimate the efficacy of continuous use of alefacept (15mg IM/week) in the treatment of moderate to severe chronic plaque type psoriasis as defined as Investigator Global Assessment (IGA) of 0 or 1 (clear or almost clear) or as a 75% reduction in Psoriasis Area and Severity Index (PASI).

Official Title

Long Term One Year Use of Alefacept (Amevive®) in Moderate to Severe Chronic Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Alefacept

Other Study ID Numbers

- IRB00004816
- 32547 Contract number

Study Start

2008 05

Primary Completion (Actual)

2009 12

Study Completion (Actual)

2010 01

Enrollment (Actual)

15

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

North Carolina Locations

Winston-Salem, North Carolina, United States, 27157
Wake Forest University Health Sciences

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Must give written informed consent.
- Subjects must be 18 years of age or older.
- Subject must be adult males or non pregnant, non lactating females.
- Female subjects of childbearing potential must state that they are using measures to avoid conception through active means including hormone replacement, intrauterine device, or abstinence.
- Subjects must be in general good health with no other skin disease, disease state or physical condition which would impair evaluation of psoriasis or which would increase their health risk by study participation.
- Subjects must be willing to receive an IM injection per protocol for 1 year.
- Must require systemic therapy or phototherapy for their psoriasis, as determined by the investigator prior to Visit 1. Objectively this equates to

Inclusion criteria of either:

- IGA≥3 on a 0 5 scale and BSA≥10%
- PASI ≥12
    - Subjects may not be taking any other systemic therapies or receiving phototherapy during the duration of the study. Subjects are required a 4 week washout period from any systemic medication or phototherapy prior to enrolling in the study and starting treatment with alefacept.
    - There is no washout for topical corticosteroid medications. Stable dosing of topical corticosteroids may be used up until the first dosing visit.

Exclusion Criteria:

- Female subjects who are not postmenopausal for at least 1 year, surgically sterile, or willing to practice effective contraception during the study. Nursing mothers, pregnant women and women planning to become pregnant while on study are to be excluded.
- Subjects have guttate, pustular, erythrodermic or rapidly flaring psoriasis.
- Current enrollment in any research study.
- Serious local infection (e.g., cellulitis, abscess) or systemic infection (e.g., pneumonia, septicemia) within the 3 months prior to the first dose of investigational drug.
- Any subject who has a CD4<250 cells/µL at study entry.
- Treatment with another investigational drug or approved therapy within 28 days prior to study drug administration.
- Treatment with systemic retinoids, systemic steroids, methotrexate, cyclosporine, azathioprine, thioguanine, etanercept, efalizumab, infliximab, adalimumab or mofetil or other systemic immunosuppressant agents within the 28 days prior to investigational drug administration.
- Phototherapy, including Ultraviolet B (UVB) and Psoralen + Ultraviolet A (PUVA), within 28 days prior to investigational drug administration.

- Known HIV+, known viral Hepatitis infection, known tuberculosis infection.
- History of systemic malignancy.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Alefacept Alefacept s FDA indication is for the treatment of adult subjects with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The approved dosing regimen is 15mg once weekly as an intramuscular injection or 7.5mg given once weekly as an intravenous bolus. The recommended regimen is a course of 12 weeks.	Drug: Alefacept • Alefacept s FDA indication is for the treatment of adult subjects with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The approved dosing regimen is 15mg once weekly as an intramuscular injection or 7.5mg given once weekly as an intravenous bolus. The recommended regimen is a course of 12 weeks. Alefacept is supplied as a lyophilized powder. Alefacept contains LFA3-IgG1 Fusion Protein and excipient materials (citrate, glycine and sucrose). • Other Names: ◦ Amevive®

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Efficacy	Efficacy of continuous use of alefacept as defined as the number of participants with a 75%	52 weeks

	reduction in Psoriasis Area and Severity Index (PASI) score from Baseline to week 52	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Safety of Alefacept Using CD4 Counts	Number of participants experiencing CD4 cell counts below 250/uL	52 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Wake Forest University

Collaborators

No information provided

Investigators

- Principal Investigator: Steven Feldman, MD, Wake Forest University

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2008-04-04

First Submitted that Met QC Criteria
2008-04-04

First Posted (Estimated)
2008-04-10

Results Reporting Dates

Results First Submitted
2012-06-27

Results First Submitted that Met QC Criteria
2012-06-27

Results First Posted (Estimated)
2012-08-03

Study Record Updates

Last Update Submitted that met QC Criteria
2018-08-13

Last Update Posted
2018-09-11

Last Verified
2018-08

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Immunologic Factors
Physiological Effects of Drugs
Alefacept

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Safety and Efficacy Study of Ustekinumab in Patients With Plaque Psoriasis Who Have Had an Inadequate Response to Methotrexate (TRANSIT)

ClinicalTrials.gov ID NCT01059773

Sponsor Janssen Cilag International NV

Information provided by Janssen Cilag International NV (Responsible Party)

Last Update Posted 2014 11 24

Study Details Tab

Study Overview

Brief Summary

This purpose of this study is to assess the safety of ustekinumab in psoriasis patients who receive ustekinumab following an inadequate response to methotrexate therapy. The study will provide

Feedback

information for doctors on how to manage the transfer from methotrexate to the biologic agent ustekinumab. The study is designed to compare two methods of transferring patients from methotrexate to ustekinumab. The two methods being compared are discontinuation of methotrexate with immediate initiation of ustekinumab versus initiation of ustekinumab with overlap and gradual dose reduction of methotrexate over 4 weeks.

Detailed Description

Only limited data exist to guide physicians on transitioning patients onto biologic agents once conventional systemic agents have been found to be inadequate. Most Phase III regulatory studies for biologics, including ustekinumab, required washout periods of between one and three months between previous therapies and the start of study agent. Although advantageous from a methodological perspective, this approach does not appear to mirror real world clinical practice, in which clinicians and patients are unwilling to go without treatment for extended periods. As a result, physicians appear to employ several arbitrary strategies when transitioning their patients. Two commonly used approaches are: Initiation of biologic therapy with immediate cessation of previous conventional systemic therapy or Initiation of biologic therapy with overlap and gradual reduction of previous conventional systemic therapy. Some physicians opt for the first strategy to minimise the risk of drug drug interactions. Others opt for the second strategy to minimise the risk of symptomatic worsening between cessation of previous treatment and the onset of action of biologic agents. This study aims to compare safety, efficacy and quality of life outcomes associated with these two strategies, with follow up for 52 weeks. The primary objective of this exploratory trial is to evaluate the comparative safety through week 12 of two treatment transition strategies in patients with inadequate response to methotrexate: discontinuation of methotrexate with immediate initiation of ustekinumab versus initiation of ustekinumab with overlap and gradual dose reduction of methotrexate over 4 weeks. Secondary objectives of the study include evaluating the safety, efficacy, and quality of life through Week 52. The focus of the trial is on estimation rather than on hypothesis testing and, therefore, no formal hypothesis testing is planned. The primary endpoint is the proportion of patients experiencing one or more treatment emergent adverse events (AEs) through Week 12 within each treatment transition arm. All proportions will be accompanied by an estimated 95% confidence interval. This is a phase IIIB/IV multicentre, open label, two arm, randomised study, lasting 56 weeks (including a screening period). The primary endpoint is assessed after 12 weeks of treatment (Week 12). All treated patients will be followed for safety and efficacy through Week 52. Patients will be stratified according to their body weight to ensure a similar distribution of patients >100 kg between the two treatment arms. Approximately 4 weeks prior to study start, all patients who provide consent for participation will be screened according to the requirements of the inclusion and exclusion criteria. Patients who meet all of the inclusion criteria and none of the exclusion criteria will enter the study. During the Screening Phase, patients will continue their current treatment schedule and dose for methotrexate, with folic acid if prescribed. At Week 0, prior to the first dose of ustekinumab, patients will be randomised 1:1 to one of the two treatment arms described below. Patients will be stratified according to their baseline body weight (=<100 kg or >100 kg) to ensure a similar distribution of patients >100 kg between the two treatment arms. Patients eligible for the study will be men and women aged 18 years or older with moderate to severe plaque psoriasis who have a Psoriasis Area and Severity Index (PASI) >=10, who have failed or are intolerant to methotrexate therapy. Patients entering the study must be receiving methotrexate at a dose of 10 25 mg/week, and should have been receiving methotrexate

for at least 8 weeks prior to screening. Approximately 576 patients will be included in the study from approximately 100 sites in 20 countries. In both treatment arms, Patients weighing ≤ 100 kg will receive ustekinumab 45 mg at Weeks 0, 4 and 16. Patients who achieve a PASI 75 response at Week 28 and 40 will continue receiving ustekinumab 45 mg at Week 28 and 40. Patients who fail to achieve PASI 75 response at Week 28 will receive ustekinumab 90 mg at Week 28 and 40. Patients who achieve a PASI 75 response at Week 28, but fail to achieve PASI 75 response at Week 40 will receive ustekinumab 90 mg at Week 40. Patients > 100 kg will receive ustekinumab 90 mg at Weeks 0, 4, 16, 28 and 40, regardless of achievement of PASI 75 response. Consideration will be given to discontinuing treatment in these patients if they show no response at Week 28. At Week 0, all eligible patients will be randomised to one of the following treatment regimens. The methotrexate dose reduction regime will depend on the dose of methotrexate at screening. All patients will stop methotrexate regardless of the final dose after 4 overlapping weeks (Weeks 0, 1, 2 and 3). The last dose of methotrexate will be given within the 7 day period before the second dose of ustekinumab. Safety evaluations will include physical examination, body weight and waist circumference, pregnancy testing, vital signs, clinical laboratory testing with full blood analysis and biochemistry, skin assessment for suspicious malignant lesions, Tuberculosis (TB) assessment, adverse events review and collection. Efficacy evaluations, including Psoriasis Area Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI) and Physicians Global Assessment (PGA), will be carried out. Evaluations to assess changes in quality of life, including the Dermatology Life Quality Index (DLQI), Hospital Anxiety Depression Score (HADS), EuroQol 5 dimensional questionnaire (EQ 5D) and Patient Benefit Index (PBI), will be carried out.

Official Title

An Exploratory Trial to Assess Naturalistic Safety and Efficacy Outcomes in Patients With Moderate to Severe Plaque Psoriasis Transitiioned to Ustekinumab From Previous Methotrexate Therapy (TRANSIT)

Conditions

Psoriasis

Intervention / Treatment

- Drug: Ustekinumab
- Drug: Methotrexate

Other Study ID Numbers

- CR016639
- CR016639 (Registry Identifier) (REGISTRY: ClinicalTrials.gov)
- CNTO1275PSO4004 (Other Identifier) (OTHER: Janssen CTMS ID)

Study Start

2009 10

Primary Completion (Actual)

2010 11

Study Completion (Actual)

2011 08

Enrollment (Actual)

490

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Methotrexate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Methotrexate) Ustekinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ustekinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Austria

Wien, Austria

Belgium

- Brussels, Belgium
- Gent, Belgium
- Liège, Belgium

Bulgaria

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Patients should have diagnosis of plaque type psoriasis for at least 6 months prior to first administration of study agent (patients with concurrent psoriatic arthritis may be enrolled)
- Moderate to severe psoriasis scored as PASI >= 10 at screening and at the time of first administration of ustekinumab
- Should currently receive (and have been receiving for at least 8 weeks directly prior to screening) systemic therapy with methotrexate at a dose of at least 10 mg/week but not exceeding 25 mg/week, with an inadequate response to this treatment (due to either efficacy or tolerability) and, in the judgment of the treating physician and patient, a treatment change is needed
- Women should take adequate birth control measures throughout the study and must agree to continue to use such birth control measures and not to become pregnant or plan to become pregnant for at least 15 weeks after the last dose of ustekinumab and for at least 6 months after the last dose of methotrexate
- Men must be using adequate birth control measures whilst receiving methotrexate and for 6 months after the last dose of methotrexate

Exclusion Criteria:

- Patients should not have non plaque forms of psoriasis (eg, erythrodermic, guttate, or pustular)
- Should currently (and within 12 months) not receive ciclosporin, fumarates, PUVA, etanercept, efalizumab, infliximab, adalimumab or alefacept or other biologic or systemic therapy (and other therapy as indicated in the protocol)
- Women who are pregnant, breastfeeding, or planning pregnancy (both men and women) while enrolled in the study
- Have previously failed treatment with any therapeutic agent directly targeted at reducing IL 12 or IL 23, including, but not limited to, ustekinumab and ABT 874
- Active or latent Tuberculosis or other chronic or recurrent infectious disease
- Known history of lymphoproliferative disease
- Known malignancy or history of malignancy

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Immediate Methotrexate Cessation Patients will receive ustekinumab by SC injection at Weeks 0, 4, 16, 28 and 40. The last dose of methotrexate will be taken anytime in the week prior to baseline (week 0).	Drug: Ustekinumab • Patients weighting ≤ 100 kg will receive ustekinumab 45 mg at Weeks 0, 4 and 16. Patients who achieve a PASI 75 response at Week 28 and 40 will continue receiving ustekinumab 45 mg at Week 28 and 40. Patients who fail to achieve PASI 75 response at Week 28 will receive ustekinumab 90 mg at Week 28 and 40. Patients who achieve a PASI 75 response at Week 28, but fail to achieve PASI 75 response at Week 40 will receive ustekinumab 90 mg at Week 40. Patients > 100 kg will receive ustekinumab 90 mg at Weeks 0, 4, 16, 28 and 40, regardless of achievement of PASI 75 response. Consideration will be given to discontinuing treatment in these patients if they show no response at Week 28.
Active Comparator: Gradual Reduction of Methotrexate Patients will receive ustekinumab by SC injection at Weeks 0, 4, 16, 28 and 40. Patients will gradually reduce the dose of methotrexate over the 4 week period after week 0.	Drug: Ustekinumab • Patients weighting ≤ 100 kg will receive ustekinumab 45 mg at Weeks 0, 4 and 16. Patients who achieve a PASI 75 response at Week 28 and 40 will continue receiving ustekinumab 45 mg at Week 28 and 40. Patients who fail to achieve PASI 75 response at Week 28 will receive ustekinumab 90 mg at Week 28 and 40. Patients who achieve a PASI 75 response at Week 28, but fail to achieve PASI 75 response at Week 40 will receive ustekinumab 90 mg at Week 40. Patients >

	100 kg will receive ustekinumab 90 mg at Weeks 0, 4, 16, 28 and 40, regardless of achievement of PASI 75 response. Consideration will be given to discontinuing treatment in these patients if they show no response at Week 28. Drug: Methotrexate • Gradual reduction of methotrexate therapy over the 4 week period after Week 0. The methotrexate dose reduction regime will depend on the dose of methotrexate at screening. All patients will stop methotrexate regardless of the final dose after 4 overlapping weeks. The last dose of methotrexate will be given within the 7 day period before the second dose of ustekinumab.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients Experiencing One or More Adverse Events Occurring From Week 0 Through Week 12		from week 0 to week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Rate of Adverse Events (AEs), Serious AEs (SAEs) and Deaths During the Study Period	The number of patients with any of the following Treatment Emergent AEs (TEAEs) were summarized through Week 12 and through Week 52, by treatment arm and body weight category (≤100 kg and >100 kg): AE; SAE and Death.	at week 12, 16, 28 40 and 52
Rate of Severe AEs, Reasonably Related AEs, and AEs Leading to Discontination During the Study Period	The number of patients with any of the following TEAEs were summarized through Week 12 and through Week 52, by treatment arm and body weight category (≤100 kg and >100 kg): AE with severe intensity; AE or SAE reasonably related to ustekinumab (i.e., AEs classified by the investigator as possibly , probably , or very likely related to study agent); AE or SAE leading to permanent discontinuation of ustekinumab.	at week 12, 16, 28 40 and 52
Rate of Infections, Severe Infections and Infections Requiring Oral or Parenteral Antimicrobial Treatment During the Study Period	The number of patients with any of the following TEAEs were summarized through Week 12 and through Week 52, by treatment arm and body weight category (≤100 kg and >100 kg): infections, serious infections, and infections requiring oral or parenteral antimicrobial treatment (infections being considered any event that by the investigator was indicated as infection on the CRF).	at week 12, 16, 28 40 and 52
Rate of Malignancies and Other Events of Clinical Interest (Tuberculosis, Serious Cardiovascular Events, Anaphylactic/Serum Sickness Reaction)	The number of patients with a malignancy and other event of clinical interest (tuberculosis, serious cardiovascular events, anaphylactic/serum sickness reaction) were summarized through Week 12 and through Week 52, by treatment arm and body weight category (≤100 kg and >100 kg)	at week 12, 16, 28 40 and 52

Change in Mean Psoriasis Area-and-severity Index (PASI) Score Compared to Baseline	Change from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]). The PASI is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	at Weeks 0, 2, 4, 12, 16, 28, 40 and 52
Proportion of Patients Achieving PASI 50 Response	This is based on the number of participants achieving at least 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]). The PASI is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	at Weeks 2, 4, 12, 16, 28, 40 and 52
Proportion of Patients Achieving PASI 75 Response	This is based on the number of participants achieving at least 75% improvement from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]). The PASI is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	at Weeks 2, 4, 12, 16, 28, 40 and 52
Proportion of Patients Achieving PASI 90 Response	This is based on the number of participants achieving at least 90% improvement from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]). The PASI is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	at Weeks 2, 4, 12, 16, 28, 40 and 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Janssen-Cilag International NV

Collaborators

No information provided

Investigators

- Study Director: Janssen Cilag International NV Clinical Trial, Janssen Cilag International NV

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-01-28

First Submitted that Met QC Criteria
2010-01-28

First Posted (Estimated)
2010-02-01

Results Reporting Dates

Results First Submitted
2011-12-22

Results First Submitted that Met QC Criteria
2011-12-22

Results First Posted (Estimated)
2012-01-30

Study Record Updates

Last Update Submitted that met QC Criteria
2014-11-13

Last Update Posted (Estimated)
2014-11-24

Last Verified
2014-11

More Information

Terms related to this study

Keywords Provided by Janssen-Cilag International NV

Psoriasis
Ustekinumab
Stelara
Methotrexate
Biologic

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents

Physiological Effects of Drugs
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Immunosuppressive Agents
Immunologic Factors
Antirheumatic Agents
Nucleic Acid Synthesis Inhibitors
Methotrexate
Ustekinumab

Study Documents

No study documents available

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Blue Light for Treating Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT02004847**

Sponsor Philips Electronics Nederland BV

Information provided by Philips Electronics Nederland BV (Responsible Party)

Last Update Posted 2015 12 18

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine the efficacy and safety of a blue light device for treating Psoriasis vulgaris. The study will compare a blue light treated plaque with an untreated control plaque. Additionally, two intensities of blue light are compared.

Feedback

Detailed Description

Blue light has been shown to release bioactive nitric oxide (NO) from nitrite and nitrosated proteins found in high concentrations in the skin. This bioactive NO has many physiological functions regulating immune responses, proliferation / differentiation as well as local blood Perfusion of the skin. The study will test the PSO CT02 device, an new investigational medical device emitting blue light with a peak wavelength of 453nm on treating localised mild Psoriasis vulgaris. It can be worn on the Skin above the effected skin area. In this study Treatment (target) and control area as well as intensity of blue light are randomized. The control area will serve as reference. 50 Patients will treat the target area daily (at least 5 times/week) at home for an initial treatment period of 4 weeks. During those 4 weeks, patients will return to the study site for safety and effectiveness assessments twice. After this initiation period patients will treat their plaque for further 8 weeks (3 times/week). This is followed by a 4 week follow up phase without treatment.

Official Title

Monocenter, Randomized, Double Blinded, Intraindividual, Exploratory Study of Effectiveness and Safety of 3 Months Treatment With 2 Peak Intensities of 453nm Blue Light for the Treatment of Mild Plaque Type Psoriasis Vulgaris

Conditions

Psoriasis Vulgaris

Intervention / Treatment

- Device: PSO CT02

Other Study ID Numbers

- PsoriasisCT02

Study Start

2013 09

Primary Completion (Actual)

2014 05

Study Completion (Actual)

2014 05

Enrollment (Actual)

47

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Germany

Aachen, Germany, 52074
Department of Dermatology and Allergology, Medical faculty of the RWTH Aachen

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Signed and dated informed consent prior to any study mandated procedure
2. Good health according to physical examination as determined by the Investigator
3. Willing and able to comply with study requirements
4. Skin type I IV according to Fitzpatrick
5. Mild plaque type psoriasis vulgaris with a Psoriasis area severity index (PASI) ≤10 and Body surface area (BSA)

   ≤10 and Dermatology Life quality index (DLQI) ≤ 10 at screening.
6. Presence of two comparable psoriatic plaques suitable to be defined as study areas as follows:
   1. located on extremities (plaques located on the palms or sole of the feet are not suitable)
   2. Both areas located either on lower or upper extremity
   3. Can be located on the same extremity
   4. Distance between the two study areas > 10cm (border to border)
   5. If lesion is too large to be fully covered, partial treatment possible
7. Aged ≥ 18 years up to <75 years
8. Reliable method of contraception for women of childbearing potential (i.e. low failure rate less than 1% per year; e.g. oral contraceptives, intra uterine device [IUD] or transdermal contraceptive patch)
9. Willing to abstain from excessive sun / UV exposure (e.g. sunbathe, solarium) during the course of the study.

Exclusion Criteria:

General

1. Inmates of psychiatric wards, prisons, or other state institutions
2. Investigator or any other team member involved directly or indirectly in the conduct of the clinical study
3. Participation in another clinical trial within the last 30 days
4. Pregnant or lactating women Medical History
5. Photodermatosis and/or Photosensitivity
6. Porphyria and/or hypersensitivity to porphyrins
7. Patients with current diagnosis of erythrodermic, exfoliative or pustular psoriasis
8. Congenital or acquired immunodeficiency
9. Patients with any of the following conditions present on the study areas: Malignoma of the skin or severe actinic damage of the skin, atypical naevi or signs of hyperpigmentation, viral (e.g. herpes or varicella) lesions of the skin, fungal and bacterial skin infections, parasitic infections and atrophic Skin
10. Patients with genetic deficiencies attached with increased sensitivity to light or increased risk to dermatologic cancer (i.e. Xeroderma pigmentosum, Cockayne Syndrome, Bloom Syndrome)

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: High Intensity (HI) vs control PSO-CT02 device: Light wavelength 453nm, high intensity, compared to contralateral untreated control plaque on the same patient.	Device: PSO-CT02 • The PSO-CT02 device is a non CE marked investigational medical device that is worn on the affected skin area where it irradiates the Psoriasis plaque for 30 minutes with blue light.
Experimental: Low Intensity (LI) vs control PSO-CT02 device: Light wavelength 453nm, low intensity, compared to contralateral untreated control plaque on the same patient.	Device: PSO-CT02 • The PSO-CT02 device is a non CE marked investigational medical device that is worn on the affected skin area where it irradiates the Psoriasis plaque for 30 minutes with blue light.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline (Visit 2) of the Local Psoriasis Area Severity Index (PASI) of the	In this study only the "local" PASI (also called local psoriasis severity index - LPSI) was evaluated. The investigator evaluated and graded the severity of erythema, induration, and	baseline and week 12

Target Area (High Intensity (HI) Group) as Compared to the Control Area at End of Treatment (Visit 7, Week 12).	scaliness as the key symptoms of psoriasis on the study areas using the following scale: 0 = no sign, 1 = slight, 2 = moderate, 3 = marked,4 = very marked A total severity score was calculated as the sum of the three symptom ratings (range 0-12 whereas 0 (best) - 12 (worst)).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline of the Local Psoriasis Area Severity Index (PASI) of the Target Area (High Intensity) as Compared to the Control Area at End of Treatment During the Attack Period (Week 4, Visit 5)	In this study only the "local" PASI (also called local psoriasis severity index - LPSI) was evaluated. The investigator evaluated and graded the severity of erythema, induration, and scaliness as the key symptoms of psoriasis on the study areas using the following scale: 0 = no sign, 1 = slight, 2 = moderate, 3 = marked,4 = very marked A total severity score was calculated as the sum of the three symptom ratings (range 0-12 whereas 0 (best) - 12 (worst)).	baseline and week 4
Change From Week 12 of the Local Psoriasis Area Severity Index (PASI) of the Target Area (High Intensity) as Compared to the Control Area	In this study only the "local" PASI (also called local psoriasis severity index - LPSI) was evaluated. The investigator evaluated and graded the severity of erythema, induration, and scaliness as the key symptoms of psoriasis on the study areas using the following scale: 0 = no sign, 1 = slight, 2 = moderate, 3 = marked,4 = very marked	Week 12 and week 16

at End of Follow-up	A total severity score was calculated as the sum of the three symptom ratings (range 0-12 whereas 0 (best) - 12 (worst)).	
Change From Baseline (Visit 2) of the Local Psoriasis Area Severity Index (PASI) of the Target Area (Low Intensity (LI) Group) as Compared to the Control Area by Week.	In this study only the "local" PASI (also called local psoriasis severity index - LPSI) was evaluated. The investigator evaluated and graded the severity of erythema, induration, and scaliness as the key symptoms of psoriasis on the study areas using the following scale: 0 = no sign, 1 = slight, 2 = moderate, 3 = marked,4 = very marked A total severity score was calculated as the sum of the three symptom ratings (range 0-12 whereas 0 (best) - 12 (worst)).	baseline and week 4, 12, 16
Difference in Change From Baseline of Local Psoriasis Area Severity Index (PASI) Between Target and Control Area of the High Intensity (HI) Group as Compared to the Low Intensity (LI) Group	In this study only the "local" PASI (also called local psoriasis severity index - LPSI) was evaluated. The investigator evaluated and graded the severity of erythema, induration, and scaliness as the key symptoms of psoriasis on the study areas using the following scale: 0. = no sign 1. = slight 2. = moderate 3. = marked 4. = very marked A total severity score was calculated as the sum of the three symptom ratings (range 0-12).	baseline and week 4, 8, 16
Change From Baseline of Erythema Evaluated by	Erythema was measured directly after treatment. Mexameter readings ranged from 0 to 100. Higher values describe higher erythema levels.	baseline and week 4, 12

Mexameter of the Target Area of High Intensity (HI) and Low Intensity (LI) as Compared to the Control Area		
Change From Week 12 (End of Treatment) of Erythema Evaluated by Mexameter of the Target Area of High Intensity (HI) and Low Intensity (LI) as Compared to the Control Area at End of Follow-up	Erythema was measured directly after treatment. Mexameter readings ranged from 0 to 100. Higher values describe higher erythema levels.	week 12 and week 16
System Usability Scale	At the end of treatment (visit 7), the usability of the investigational device was evaluated by a questionnaire presented to the patient in German. The usability was evaluated by using the System Usability Scale (SUS) which is an effective tool for assessing the usability of a device. It provides an easy-to-understand score from 0 (negative) to 100 (positive).	week 12
Change From Baseline in Dermatology Life Quality Index (DLQI)	It is a simple 10-question validated questionnaire. The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired. As the change from baseline is calculated negative values in the Outcome	baseline and week 12

	Measure Data indicate an improvement in quality of life.	
Time to First Use of Topical Co-treatment With Vitamin D of High Intensity (HI) and Low Intensity (LI)		patients will be followed for the complete duration of the clinical study for 16 weeks
Total Duration of Topical Co-treatment With Vitamin D of High Intensity (HI) and Low Intensity (LI)		week 16
Adverse Device Events (Serious and Non-serious)	Adverse device events: Adverse event related to the use of an investigational medical device wich led to any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons. Serious adverse device event: Adverse device effect that has resulted in a) led to death, b) led to serious deterioration in the health of the subject, that either resulted in 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function, or 3) in-patient or prolonged hospitalization, or 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body	week 0, 1, 2, 4, 8, 12, 16

	structure or a body function, c) led to foetal distress, foetal death or a congenital abnormality or birth defect.	

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Hyperpigmentation of "Normal Skin Areas" Surrounding the Target Area Exposed to Blue Light and Control Area Not Exposed to Blue Light- Evaluation by Mexameter	Arbitrary units measured by mexameter. Mexameter readings ranged from 0 to 100. Higher values correspond to higher pigmentation levels.	week 4, 12, 16
Adverse Events (Serious and Non-serious)		week 0, 1, 2, 4, 8, 12, 16
Thermal Comfort	Questionaire	week 12
Patient Acceptance of Hyperpigmentation	Questionaire	week 16

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Philips Electronics Nederland BV

Collaborators

No information provided

Investigators

- Principal Investigator: Verena von Felbert, PD, Dr., Clinic for Dermatology and Allergology, Medical Faculty of the RWTH Aachen, Germany

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-11-19

First Submitted that Met QC Criteria
2013-12-03

First Posted (Estimated)
2013-12-09

Results Reporting Dates

Results First Submitted

2015-08-12

Results First Submitted that Met QC Criteria

2015-10-14

Results First Posted (Estimated)

2015-11-18

Study Record Updates

Last Update Submitted that met QC Criteria

2015-11-17

Last Update Posted (Estimated)

2015-12-18

Last Verified

2015-11

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Judging the Efficacy of Secukinumab in Patients With Psoriasis Using AutoiNjector: a Clinical Trial Evaluating Treatment Results (JUNCTURE) (JUNCTURE)

ClinicalTrials.gov ID **NCT01636687**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2018 09 27

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study was to demonstrate efficacy of autoinjector administered secukinumab at Week 12 based on PASI and IGA response rates versus placebo in subjects with moderate to severe chronic plaque type psoriasis.

Official Title

A Randomized, Double blind, Placebo Controlled, Multicenter Study of Subcutaneous Secukinumab in Autoinjectors to Demonstrate Efficacy After Twelve Weeks of Treatment, and to Assess the Safety, Tolerability, Usability and Long term Efficacy in Subjects With Chronic Plaque type Psoriasis

Conditions

Plaque type Psoriasis

Intervention / Treatment

- Drug: Placebo
- Drug: Secukinumab 150mg
- Drug: Secukinumab 300mg

Other Study ID Numbers

- CAIN457A2309
- 2012 002609 22 (EudraCT Number)

Study Start (Actual)

2012 10 17

Primary Completion (Actual)

2016 10 27

Study Completion (Actual)

2016 10 27

Enrollment (Actual)

182

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arizona Locations

Phoenix, Arizona, United States, 85032
Novartis Investigative Site

California Locations

Los Angeles, California, United States, 90045
Novartis Investigative Site

Oceanside, California, United States,

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion criteria:

- Moderate and severe plaque type psoriasis diagnosed for at least 6 months.
- Severity of psoriasis disease meeting all of the following three criteria:
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater
  - Investigator s Global Assessment (IGA) score of 3 or greater
  - Total body surface area (BSA) affected of 10% or greater
- Inadequate control by prior use of topical treatment, phototherapy and/or systemic therapy.

Exclusion criteria:

- Current forms of psoriasis other than chronic plaque type psoriasis (for example, pustular, erythrodermic, guttate).
- Current drug induced psoriasis.
- Previous use of secukinumab or any drug that targets IL 17 or IL 17 receptor.
- Significant medical problems such as uncontrolled hypertension, congestive heart failure or a condition that significantly immunocompromises the subject.
- Hematological abnormalities.
- History of an ongoing, chronic or recurrent infectious disease, or evidence of untreated tuberculosis.
- History of lymphoproliferative disease or history of malignancy of any organ system within the past 5 years.
- Pregnant or nursing (lactating) women.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo Subjects who were in placebo at Week 52 cannot continue in the extension treatment period	Drug: Placebo • 2 injections of placebo to secukinumab 150mg per dose
Experimental: Secukinumab 150 mg After the data base lock of week 52 data has been performed, subjects received secukinumab 150 mg treatment as open label for the remainder of the extension treatment period.	Drug: Secukinumab 150mg • Secukinumab 150mg: 1 injection of 150 mg secukinumab and 1 injection of placebo to secukinumab 150mg per dose. After Week 52 database lock, study is open label so only 1 injection of secukinumab 150mg per dose were administered
Experimental: Secukinumab 300 mg After the data base lock of week 52 data has been performed, subjects received secukinumab 300 mg treatment as open label for the remainder of the extension treatment period.	Drug: Secukinumab 300mg • Secukinumab 300mg (2 injections of 150mg secukinumab per dose)

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area and Severity Index (PASI) 75 Response and Investigators Global Assessment (IGA) Mod 2011 0 or 1 Response	Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis. PASI score was based on assessment of the head, trunk, upper limbs and lower limbs for erythema, thickening (plaque elevation, induration), and scaling (desquamation). PASI scores can range from 0, corresponding to no signs of psoriasis, up to a theoretical maximum of 72.0. PASI-based secondary variables included absolute PASI score, response rates for PASI 75. PASI 50 and PASI 90 were defined as ≥ 50% and ≥ 90% improvement from Baseline in PASI score, respectively, while PASI 100 response corresponded to complete clearing of psoriasis (PASI = 0). IGA mod 2011 was used to evaluate the overall severity of psoriatic disease, with scores ranging from 0 (clear) to 4 (severe). Treatment success was defined as achievement of IGA mod 2011 0 or 1 score.	12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentages of Subjects With Successful Self-administration	To assess the subject s ability to follow instructions for use with the secukinumab autoinjector	Week 1

of Study Drug at Week 1		
Percentage of Subjects With Possible Use-related Hazards	To assess potential use-related hazards with the secukinumab autoinjector for the subject.	Week 1
Absolute Change From Baseline in Self-Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 12	The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10; "0" corresponds to worst experience while "10" corresponds to best experience. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.	Week 12
Absolute Change From Baseline in Self-Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 48	The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10; "0" corresponds to worst experience while "10" corresponds to best experience. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.	Absolute change from baseline at week 48
Percentages of Participants With PASI 50, PASI 75, PASI 90, PASI 100 and IGA Mod	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and	Week 12

2011 0 or 1 Response - Induction Period	scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Percentages of Participants With PASI 50, PASI 75, PASI 90, PASI 100 and IGA Mod 2011 0 or 1 Response - Maintenance Period (Observed Data)	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare	Week 12 up to Week 52

	with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Absolute Change From Baseline for PASI Score - Induction Period	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head:01, arms:0.2 body:0.3 legs:0.4)	Baseline, Week 12
Absolute Change From Baseline for PASI Score Over Time up to Week 52 - Maintenance Period (Observed Data)	Psoriasis Area and Severity Index (PASI): Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head:01, arms:0.2 body:0.3 legs:0.4).	Baseline, Week 52
Percentage of Participants in Each IGA Mod 2011 Category - Induction Period	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 =	Week 12

	clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe	
Percentages of Participants in Each IGA Mod 2011 Category Over Time up to Week 52 - Maintenance Period (Observed Data)	The Investigators Global Assessment (IGA) mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	Week 52
Change From Baseline in EQ-5D up to Week 12 - Induction Period	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state).	Week 12
Change From Baseline in EQ-5D Over Time up to Week 52 - Maintenance Period	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state).	Week 52

Percentage Changes From Baseline in Dermatology Life Quality Index (DLQI) Score - Induction Period	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions. A negative median percent change from baseline indicates improvement.	Baseline, up to Week 12
Percentage Changes From Baseline in Dermatology Life Quality Index (DLQI) Score Over Time up to Week 52 - Maintenance Period	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions. A negative median percent change from baseline indicates improvement.	Baseline, Week 52
Percentage of Participants Achieving a DLQI Score of 0 or 1 at Week 12 - Induction Period	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0	Week 12

	(not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions.	
Percentages of Participants Achieving a DLQI Score of 0 or 1 Over Time up to Week 52 - (Maintenance)	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions.	Week 52

Percentages of Participants With PASI 50, PASI 75, PASI 90, PASI 100 and IGA Mod 2011 0 or 1 Response After Week 52 (Observed Data)	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	Week 160
Absolute Change From Baseline for PASI Score After Week 52 (Observed Data)	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head:01, arms:0.2 body:0.3 legs:0.4).	Week 160

Percentages of Participants in Each IGA Mod 2011 Category After Week 52 (Observed Data)	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	Week 160
Number of Participants Developing Treatment-emergent Anti-secukinumab Antibodies	The development of anti-secunimubab anti-bodies decreases a participant s ability to respond to secukinumab treatment. The number of participants developing anti-secukinumab anti-bodies was measured from Baseline to week 216.	Baseline and at Week 12, 24, 52, 100, 148, 196, 208, and 216

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-07-06

First Submitted that Met QC Criteria
2012-07-09

First Posted (Estimated)
2012-07-10

Results Reporting Dates

Results First Submitted
2017-10-23

Results First Submitted that Met QC Criteria
2018-09-26

Results First Posted
2018-09-27

Study Record Updates

Last Update Submitted that met QC Criteria
2018-09-26

Last Update Posted
2018-09-27

Last Verified

2018-09

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis
Moderate to Severe Plaque type Psoriasis
Skin condition
skin disease
itching condition
psoriasis vulgaris
relapsing/remitting psoriasis
immune mediated systemic disease
skin lesions
red skin lesions
scaly patches
papules
plaques
itching

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies, Monoclonal

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

IPD Plan Description

Novartis is committed to sharing with qualified external researchers, access to patient level data and supporting clinical documents from eligible studies. These requests are reviewed

and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Dose-Finding Study of GSK2894512 Cream in Subjects With Plaque Psoriasis

ClinicalTrials.gov ID **NCT02564042**

Sponsor GlaxoSmithKline

Information provided by GlaxoSmithKline (Responsible Party)

Last Update Posted 2017 11 13

Study Details Tab

Study Overview

Brief Summary

This study will evaluate the efficacy and safety of two concentrations (0.5 percent [%] and 1%) and two application frequencies (once a day and twice a day) of GSK2894512 cream for the topical treatment in subjects with plaque psoriasis. Results from this study will be considered when

Feedback

selecting the most appropriate concentration of GSK2894512 cream and dosing frequency in future clinical safety and efficacy studies. This is a multicenter (United States, Canada, and Japan), randomized, double blind (sponsor unblind), vehicle controlled, 6 arm, parallel group, dose finding study. Two concentrations of GSK2894512 cream (0.5% and 1%) and a vehicle control cream will be equally randomized and evaluated following application to all psoriasis lesions (except on the scalp) once daily (evening) or twice daily (morning and evening) for 12 weeks. This study will consist of 3 periods: up to 4 weeks screening, 12 weeks double blind treatment, and 4 weeks post treatment follow up. The total duration of subject participation will be approximately 16 to 20 weeks. Approximately 270 adult males and females subjects with plaque psoriasis will be screened in order to have at least 228 randomized subjects (38 subjects for each of the 6 treatment groups) and approximately 204 evaluable subjects overall. Approximately 30 subjects will be randomized in Japan to achieve at least 24 evaluable Japanese subjects.

Official Title

Study 203120: A Randomized, Blinded, Vehicle Controlled, Dose Finding Study of GSK2894512 Cream for the Treatment of Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: GSK2894512 1% Cream
- Drug: GSK2894512 0.5% Cream
- Drug: Vehicle cream

Other Study ID Numbers

- 203120

Study Start

2015 11 23

Primary Completion (Actual)

2016 10 01

Study Completion (Actual)

2016 10 05

Enrollment (Actual)

227

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

San Diego, California, United States, 92123
GSK Investigational Site

Connecticut Locations

North Logan, Connecticut, United States, 06032
GSK Investigational Site



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Male or female between 18 to 65 years of age inclusive, at the time of signing the informed consent.
- Confirmed clinical diagnosis of chronic stable plaque psoriasis for >=6 months.
- Body surface area involvement >=1% and <=15%, excluding scalp, at Screening and Baseline.
- A PGA of psoriasis score >=2 at Baseline.
- One target plaque located on the trunk or proximal parts of extremities (excluding knees, elbows, and intertriginous areas) that is at least 3 (centimetre) cm x 3 cm in size at Screening and Baseline with a severity representative of the subject s overall disease.
- A female subject is eligible to participate if she is not pregnant (as confirmed by a negative urine human chorionic gonadotrophin test), not lactating, and at least one of the following conditions applies: Non reproductive potential defined as: 1) Pre menopausal females with one of the following procedures documented: tubal ligation; hysteroscopic tubal occlusion procedure with follow up confirmation of bilateral tubal occlusion; hysterectomy; bilateral oophorectomy. 2) Post menopausal defined as 12 months of spontaneous amenorrhea (in questionable cases a blood sample with simultaneous follicle stimulating hormone and estradiol levels consistent with menopause and falling into the central laboratory s postmenopausal reference range is confirmatory). Females on hormone replacement therapy (HRT) and whose menopausal status is in doubt are required to use one of the highly effective contraception methods if they wish to continue their HRT during the study. Otherwise, they must discontinue HRT to allow confirmation of post menopausal status prior to study enrolment; Reproductive potential and agrees to follow one of the options listed in the modified list of highly effective methods for avoiding pregnancy in females of reproductive potential from 30 days prior to the first dose of study medication and until (at least five terminal half lives OR until any continuing pharmacologic effect has ended, whichever is longer) after the last dose of study medication and completion of the follow up visit.

Exclusion Criteria:

- Any sign of infection of any of the psoriatic lesions.
- A history or ongoing serious illness or medical, physical, or psychiatric condition(s) that, in the investigator s opinion, may interfere with the subject s completion of the study.
- Known hypersensitivity to the study treatment excipients, or a history of drug or other allergy that, in the opinion of the investigator, contraindicates participation.
- Current or chronic history of liver disease, known hepatic or biliary abnormalities (with the exception of Gilbert s syndrome or asymptomatic gallstones), presence of hepatitis B surface antigen, or positive hepatitis C antibody test result within 3 months of screening.
- Liver function tests: alanine aminotransferase >=2x upper limit of normal (ULN); alkaline phosphatase and bilirubin >1.5xULN (isolated bilirubin >1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%).

- QTc >=450 milliseconds (msec) or QTc >=480 msec for subjects with bundle branch block.

NOTES: The QTc is the QT interval corrected for heart rate according to Fridericia s formula (QTcF), with machine over read. The QTc should be based on a single ECG obtained over a brief recording period. If QTc is outside of the threshold value, triplicate ECGs may be performed with the QTc values averaged.

- Ultraviolet (UV) light therapy or prolonged exposure to natural or artificial sources of UV radiation (eg, sunlight or tanning booth) within 4 weeks prior to the baseline visit and/or intention to have such exposure during the study, which is thought by the investigator to potentially impact the subject s psoriasis.
- Used any of the following treatments within the indicated washout period before the baseline visit: 1) 12 weeks or 5 half lives (whichever is longer) biologic agents (eg, 24 weeks for alefacept, 12 weeks for etanercept, 15 weeks for ustekinumab); 2) 12 weeks oral retinoids (eg, acitretin or isotretinoin); 3) 8 weeks cyclosporin, interferon, methotrexate, other systemic immunosuppressive or immunomodulating agents, or psoralen plus UVA light treatment; 4) 4 weeks systemic corticosteroids or adrenocorticotropic hormone analogs; 5) 2 weeks immunizations; drugs known to possibly worsen psoriasis, such as beta blockers (eg, propranolol), lithium, iodides, angiotensin converting enzyme inhibitors, and indomethacin, unless on a stable dose for >12 weeks; 6) 2 weeks topical treatments: corticosteroids, immunomodulators, anthralin (dithranol), Vitamin D derivatives, retinoids, or coal tar (used on the body).
- Participated in a clinical study and received an investigational product within the following time period prior to the baseline visit: 4 weeks, 5 half lives, or twice the duration of the biological effect of the investigational product (whichever is longer).
- History of alcohol or other substance abuse within the last 2 years.
- Participated in a previous study using GSK2894512 (or WBI 1001).

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: GSK2894512 1% cream twice daily Subjects will apply a thin layer of GSK2894512 1% (10 milligram per gram [mg/g]) topical cream twice daily (morning and evening) for 12 weeks, to all psoriasis lesions (except on the scalp).	Drug: GSK2894512 1% Cream • 1.0% (10 mg/g) GSK2894512 will be supplied as white to off-white cream to be applied topically
Experimental: GSK2894512 1% cream once daily Subjects will apply a thin layer of GSK2894512 1% (10 mg/g) topical cream once daily (evening) for 12 weeks, to all psoriasis lesions (except on the scalp).	Drug: GSK2894512 1% Cream • 1.0% (10 mg/g) GSK2894512 will be supplied as white to off-white cream to be applied topically
Experimental: GSK2894512 0.5% cream twice daily Subjects will apply a thin layer of GSK2894512 0.5% (5 mg/g) topical cream	Drug: GSK2894512 0.5% Cream • 0.5% (5 mg/g) GSK2894512 will be supplied as white to off-white cream to be applied topically

twice daily (morning and evening) for 12 weeks, to all psoriasis lesions (except on the scalp).	
Experimental: GSK2894512 0.5% cream once daily Subjects will apply a thin layer of GSK2894512 0.5% (5 mg/g) topical cream once daily (evening) for 12 weeks, to all psoriasis lesions (except on the scalp).	Drug: GSK2894512 0.5% Cream • 0.5% (5 mg/g) GSK2894512 will be supplied as white to off-white cream to be applied topically
Placebo Comparator: Vehicle cream twice daily Subjects will apply a thin layer of vehicle topical cream twice daily (morning and evening) for 12 weeks, to all psoriasis lesions (except on the scalp).	Drug: Vehicle cream • White to off-white vehicle cream base to be applied topically
Placebo Comparator: Vehicle cream once daily Subjects will apply a thin layer of vehicle topical cream once daily (evening) for 12 weeks, to all psoriasis	Drug: Vehicle cream • White to off-white vehicle cream base to be applied topically

lesions (except on the scalp).	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Have a Physician Global Assessment (PGA) Score of 0 or 1 at Week 12 and a Minimum 2-grade Improvement in PGA Score From Baseline to Week 12	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate and 4=Severe. The percentage of responders that is, participants who achieved a PGA score of 0 or 1 and a minimum 2-grade improvement from Baseline were summarized. Baseline was defined as the latest assessment prior to the first dose. The analysis was performed on modified intent-to-treat (mITT) Population which comprised of all randomized participants except those enrolled at center ID 220008.	Baseline and up to Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With >=75 Percent Improvement in	The PASI is a standard clinical tool for assessing the severity of psoriasis based on severity of erythema, thickness and scale, as well as the extent of body surface area (BSA)	Baseline and up to Week 16

Psoriasis Area and Severity Index (PASI) From Baseline to Each Study Visit	affected with psoriasis. The 3 clinical signs were graded on a 5 point scale (0 to 4) and the % BSA affected was scored on a 7-point scale (0 to 6) for each of the 4 specified body regions (head, upper extremities, trunk and lower extremities). The individual scores were multiplied by a weighted factor for each body region. The sum of these scores gave the overall PASI score. Higher scores indicated more severe disease. The percentage of participants with >=75% improvement in PASI from Baseline were summarized. Baseline was defined as the latest assessment prior to the first dose. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Percentage of Participants With a Minimum 2 Grade Improvement in PGA Score From Baseline to Each Study Visit	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate and 4=Severe. The percentage of participants who achieved a minimum 2-grade improvement from Baseline for each study visit were summarized. Baseline was defined as the latest assessment prior to the first dose. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 16

Percentage of Participants With a PGA Score of 0 or 1 at Each Study Visit	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate and 4=Severe. The percentage of participants who achieved a PGA score of 0 or 1 from Baseline at each study visit was summarized. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Up to Week 16
Mean Change in Percent of BSA Affected With Psoriasis From Baseline to Each Study Visit	The extent of BSA affected by psoriasis is a general indicator of disease severity and was measured throughout the study. The extent of BSA to which study treatment was applied was also recorded. For the purpose of approximate clinical estimation, the total palmar surface of the palm plus 5 digits was assumed to be approximately equivalent to 1 percent BSA. Assessment of BSA affected with psoriasis was performed separately for four body surface regions: the head, the upper extremities, the trunk and the lower extremities, corresponding to 10, 20, 30 and 40 percent of the total body area, respectively. The mean change in percent BSA affected from Baseline was summarized for each study visit. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those	Baseline and up to Week 16

	participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Mean Change in PASI Score From Baseline to Each Study Visit	The PASI is a standard clinical tool for assessing the severity of psoriasis based on severity of erythema, thickness and scale, as well as the extent of BSA affected with psoriasis. The 3 clinical signs were graded on a 5 point scale (0=None to 4=Severe) and the percent of BSA affected is scored on a 7-point scale (0=0% involvement to 6=90-100%) for each of 4 specified body regions (head, upper extremities, trunk and lower extremities). The individual scores were multiplied by a weighted factor for each body region. The sum of these scores gave the overall PASI score. PASI score ranged from 0=no psoriasis to 72=worse psoriasis. The mean change in PASI score from Baseline was summarized for each study visit. Baseline was the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 16
PGA Scores at Each Study Visit	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 =	Up to Week 16

	Mild, 3 = Moderate and 4=Severe. The mean of PGA scores at each study visit was summarized. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Mean Change in PGA Score From Baseline to Each Study Visit	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 = Mild, 3 = Moderate and 4=Severe. The mean change in PGA scores from Baseline was summarized for each study visit. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 16
Mean Change in Individual Target Lesion Grading Scores From Baseline to Each Study Visit	A single target lesion of at least 3 centimeter (cm) x 3 cm was selected at Baseline. For the selected lesion, the severity of erythema, scaling and plaque thickness (induration) was assessed by the investigator on a 5-point scale ranging from 0=none to 4=severe. The mean change in individual grading scores from Baseline was summarized for each study visit. Baseline was defined as the latest assessment prior to the first dose and change from Baseline	Baseline and up to Week 16

	was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Mean Change in Weekly Average Itch/Pruritus Numeric Rating Scale (NRS) From Baseline to Each Study Visit	The participant reported itch severity was obtained from the response of the participants to the itch NRS item in the psoriasis symptom diary (PSD). PSD was developed to assess daily self-reports of psoriasis symptoms and the functional impact related to the underlying pathophysiology of the disease. The participants answered questions related to the severity and impact of the signs and symptoms daily using a 11 point NRS with scores ranging from 0 (absent) to 10 (worst imaginable). Mean change in itch/pruritis NRS from Baseline to each study visit was presented. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the post dose weekly average value minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 16
Percentage of Participants Who Achieved a PGA Score of 0 or 1 and a Minimum 2 Grade Improvement From Baseline to Each Study Visit	The PGA is a clinical tool for assessing the current state/severity of a participant s psoriasis. It is a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness, and scaling as guidelines. Each assessment was made as a visual average of the severity of all treated areas at the time of the assessment. The scores ranged from 0 to 4 where 0 = Clear, 1 = Almost Clear, 2 =	Baseline and up to Week 16

	Mild, 3 = Moderate and 4=Severe. The percentage of responders that is, participants who achieved a PGA score of 0 or 1 and a minimum 2-grade improvement from baseline were summarized. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious TEAEs	An AE is defined as any untoward medical occurrence in a participant under clinical investigation, temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product. Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/ birth defect, other situations and is associated with liver injury or impaired liver function. A TEAE is defined as an AE which occurred on or after study treatment start date and on or before the last visit. Number of participants with AEs and SAEs were presented. The analysis was performed on safety Population which comprised of all participants who received at least one dose of study treatment.	Up to Week 16
Number of Participants With Reported Local Tolerability Scores	The assessment of the presence and degree of burning/stinging and itching at the application site following application of the study treatment was done at each specified study visit using a 5 point tolerability scale.	Up to Week 14

	The scores ranged from 0 to 4 where 0=None and 4=Strong/Severe. The score represented an average across all application sites. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	
Change From Baseline in Albumin and Protein Level	Blood samples were collected for the evaluation of change in albumin and protein levels from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Alkaline Phosphatase (Alk Phos), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), and Gamma Glutamyl Transferase (GGT) Levels.	Blood samples were collected for the evaluation of change in levels of alk phos, ALT, AST and GGT from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Direct Bilirubin (Bil), Bilirubin (Bil), Creatinine and Urate.	Blood samples were collected for the evaluation of change in levels of direct bil, bil, creatinine and urate from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data	Baseline and up to Week 14

	available at the specified data points were analyzed (represented by n=X in category title).	
Change From Baseline in Calcium, Chloride, Carbon Dioxide (CO2), Glucose, Potassium, Sodium and Urea Levels	Blood samples were collected for the evaluation of change in levels of calcium, chloride, CO2, glucose, potassium, sodium, and urea from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Platelets and Leukocyte Count	Blood samples were collected for the evaluation of change in levels of basophils, eosinophils, lymphocytes, monocytes, neutrophils, platelets and leukocyte count from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Hematocrit Levels	Blood samples were collected for the evaluation of change in hematocrit levels from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data	Baseline and up to Week 14

	points were analyzed (represented by n=X in category title).	
Change From Baseline in Hemoglobin (Hgb) Level and Erythrocyte Mean Corpuscular Hgb Concentration (MCHC)	Blood samples were collected for the evaluation of change in Hgb levels and MCHC from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Erythrocyte Mean Corpuscular Hemoglobin Level	Blood samples were collected for the evaluation of change in erythrocyte mean corpuscular hemoglobin level from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Erythrocyte Mean Corpuscular Volume	Blood samples were collected for the evaluation of change in erythrocyte mean corpuscular volume from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were	Baseline and up to Week 14

	analyzed (represented by n=X in category title).	
Change From Baseline in Erythrocyte Count	Blood samples were collected for the evaluation of change in erythrocyte count from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Number of Participants With Chemistry Data of Potential Clinical Importance	Blood samples were collected for the evaluation of clinical chemistry parameters including alk phos, ALT, AST, bil, calcium, CO2, creatinine, glucose and potassium. The number of participants with chemistry data of potential clinical importance for the mentioned parameters was presented. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Up to Week 14
Number of Participants With Hematology Data of Clinical Importance	Blood samples were collected for the evaluation of hematology parameters including hematocrit, Hgb, lymphocytes, neutrophils and platelets. The number of participants with clinically significant abnormal values of the mentioned hematology parameters was presented. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose. Only those participants with data available at the specified data	Up to Week 14

	points were analyzed (represented by n=X in category title).	
Change From Baseline in Immunoglobulin (Ig) A, IgG and IgM Levels	Blood samples were collected for the evaluation of change in IgA, IgG and IgM levels from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 12
Number of Participants With Ig Data Outside the Reference Range	Blood samples were collected for the evaluation of change in Ig levels from Baseline throughout the study. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Up to Week 12
Number of Participants With Immunophenotyping Data Outside the Reference Range	Blood samples were collected for the evaluation of change in levels of cluster of differentiation (CD)19, CD3, CD3 Treg flow cytometry (CD3TFLC), CD3+CD8+, CD3+CD8+ TFLC, CD3+CD4+, CD3+CD4+ TFLC, CD16+CD56+, CD3+CD4+CD25+CD127 flow cytometry (CD3+CD4+CD25+CD127), CD3+CD4+foxP3+CD25+CD127 flow cytometry (CD3+CD4+fP3+CD25+CD127) and T Cell B Cell Natural Killer Lymphocytes flow cytometry (T-B cell NKL). Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose. Only those participants with data available at	Up to Week 12

	the specified data points were analyzed (represented by n=X in category title).	
Change From Baseline in Immunophenotype Data	Blood samples were collected for the evaluation of change from Baseline in immunophenotype levels including CD19, CD3, CD3TFLC, CD3+CD8+, CD3+CD8+ TFLC, CD3+CD4+, CD3+CD4+ TFLC, CD16+CD56+, CD3+CD4+CD25+CD127 flow cytometry (CD3+CD4+CD25+CD127), CD3+CD4+foxP3+CD25+CD127 flow cytometry (CD3+CD4+fP3+CD25+CD127) and T-B cell NKL. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 12
Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)	SBP and DBP were measured in semi-supine position after at least 5 minutes of rest. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Change From Baseline in Pulse Rate	Pulse rate was measured in semi-supine position after at least 5 minutes of rest. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data	Baseline and up to Week 14

	available at the specified data points were analyzed (represented by n=X in category title).	
Change From Baseline in Temperature	Temperature was measured in semi-supine position after at least 5 minutes of rest. Baseline was defined as the latest assessment prior to the first dose and change from Baseline was defined as the value at post dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Baseline and up to Week 14
Number of Participants With Vital Signs of Clinical Importance	The vital signs including SBP, DBP and pulse rate were measured from Baseline throughout the study. The number of participants with clinically significant abnormal vital signs were presented. Baseline was defined as the latest assessment prior to the first dose. Only those participants with data available at the specified data points were analyzed (represented by n=X in category title).	Up to Week 14
Number of Participants With Abnormal Electrocardiogram (ECG) Findings	Single 12-lead ECGs were obtained over a brief recording period at each specified time point during the study using an ECG machine that automatically calculated the heart rate and measured PR, QRS, QT, and corrected QT (QTc) intervals. Baseline was defined as the latest assessment (including unscheduled visits) prior to the first dose. For multiple ECGs at one visit, or "Any time post-screen", a participant is categorized as "Abnormal" if >=1 assessment is abnormal. Only those participants with data available at the	Up to Week 14

	specified data points were analyzed (represented by n=X in category title).	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

GlaxoSmithKline

Collaborators

No information provided

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2015-09-28

First Submitted that Met QC Criteria
2015-09-28

First Posted (Estimated)
2015-09-30

Results Reporting Dates

Results First Submitted
2017-09-11

Results First Submitted that Met QC Criteria
2017-11-01

Results First Posted
2017-11-13

Study Record Updates

Last Update Submitted that met QC Criteria
2017-11-01

Last Update Posted
2017-11-13

Last Verified
2017-10

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline

Double blind
Dose finding
Vehicle Controlled

GSK2894512

Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous

Skin Diseases

Psoriasis

Study Documents

No study documents available

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

Subjects declined enrollment; sponsor/PI elected to close study.

Alefacept in Subjects With Chronic Plaque Psoriasis Who Failed to Respond to Anti-TNF Therapy

ClinicalTrials.gov ID **NCT00953329**

Sponsor John Murray

Information provided by John Murray, Duke University (Responsible Party)

Last Update Posted 2013 02 22

Study Details Tab

Study Overview

Brief Summary

Study Status:

Feedback

Duke University Health System Institutional Review Board has received notification of study termination; final IRB closure date is 12/12/2008. Study enrollment is now closed.

Enrollment Update:

Only one subject was entered into this study out of an expected enrollment of 15 patients in this single site clinical trial. With no recruitment interest, the financial sponsor and Sponsor PI chose to close the clinical trial.

Detailed Description

This is an open label study using alefacept in the treatment of patients with chronic plaque psoriasis who have not responded to treatment with an anti TNF agent. Patients not responding to Enbrel® 50 mg weekly with a 75% reduction of Psoriasis Area and Severity Index (PASI) Score or a Physician Global Assessment (PGA) score of almost clear or clear , will be treated with 15 mg alefacept intramuscularly (IM) once weekly for up to 20 weeks. Patients who have cleared or almost cleared at the end of 12 weeks of treatment with alefacept will have completed the standard treatment phase of the study. Study subjects who have not responded to treatment during the initial 12 weeks will continue with alefacept therapy for an additional 8 weekly doses or until the subject has reached a PGA of almost clear or clear . Alefacept is FDA approved for this indication for 12 weeks of treatment and this clinical trial is extending the treatment window for up to 8 additional weeks. Because of this increased exposure to alefacept, all subjects will be carefully monitored while on treatment and followed post treatment at 3, 4, 6, 9 and 12 months after the last dose of alefacept is given.

Purpose:

This open label study will determine the safety and efficacy of Amevive® 15 mg IM weekly in subjects with chronic plaque psoriasis who have not sufficiently responded to etanercept, an anti TNF agent. The plan also is to determine the length of response time to point of relapse and to determine the length of time before retreatment with alefacept is necessary.

Patient Population:

This study is for adult men and women, ages 18 to 80, with chronic plaque psoriasis. At the time of enrollment, the subject must have received 50 mg per week of Enbrel without achieving a response of almost clear or clear according to PGA or has not responded with a 75% reduction of PASI Score.

Official Title

An Open Label Study to Determine the Safety and Efficacy of Alefacept as Monotherapy in Subjects With Chronic Plaque Psoriasis Who Have Failed to Respond to Anti TNF Therapy

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: alefacept

Other Study ID Numbers

- Pro00002474
- Funding Agency # ER 07 001
- IND # 100770

Study Start

2008 02

Primary Completion (Actual)

2008 12

Study Completion (Actual)

2008 12

Enrollment (Actual)

1

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Men and women between ages of 18 and 80 years
- Subjects diagnosed with chronic plaque psoriasis who require systemic therapy.
- Must be receiving anti TNF treatment without achieving response of almost clear or clear according to PGA or has not responded with 75% reduction PASI score.
- Must be willing to receive up to 20 weeks of IM injections weekly
- CD4 counts must be above 250 cells/mm3 at screening

Exclusion Criteria:

- Diagnosis of unstable erythroderma or pustular psoriasis or guttate psoriasis
- Serious local infection or systemic infection 3 months prior to receiving study drug.
- Subjects with CD4 lymphocyte count less than 250 cells/mm3 at study entry

Ages Eligible for Study

18 Years to 80 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Alefacept 15 mg IM qweek Alefacept will be given to subjects with plaque psoriasis who have failed treatment with Fnbrel.	Drug: alefacept • Alefacept 15 mg IM once a week were to be administered for 12 weeks, which is the FDA approved dosage, duration, and frequency. This study allowed an additional 8 doses if subject did not achieve a clear response with the original 12 weeks of treatment. Each enrolled subject must have failed a response to anti-TNF therapy prior to entering this study. • Other Names: ◦ Amevive

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Treatment Alefacept	Terminated study	12 weeks (study terminated)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

John Murray

Collaborators

- Astellas Pharma US, Inc.

Investigators

- Principal Investigator: John C Murray, MD, Duke University

Publications

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General Publications

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Study Registration Dates

First Submitted
2009-07-22

First Submitted that Met QC Criteria
2009-08-05

First Posted (Estimated)
2009-08-06

Results Reporting Dates

Results First Submitted
2012-10-18

Results First Submitted that Met QC Criteria
2013-01-14

Results First Posted (Estimated)
2013-02-15

Study Record Updates

Last Update Submitted that met QC Criteria
2013-02-20

Last Update Posted (Estimated)
2013-02-22

Last Verified
2013-02

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Immunologic Factors
Physiological Effects of Drugs
Alefacept

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Olux E Foam and Sorilux Foam Combination Therapy for the Maintenance of Treatment Response in Patients With Moderate Plaque Psoriasis

ClinicalTrials.gov ID **NCT01745133**

Sponsor Leon Kircik, M.D.

Information provided by Leon Kircik, M.D., Derm Research, PLLC (Responsible Party)

Last Update Posted 2016 11 17

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of the study is to investigate if combined use of OLUX E™ Foam and SORILUX Foam may help "maintain" the therapeutic benefit that is achieved with OLUX E™ Foam in the treatment of moderate plaque psoriasis.

OLUX E™ is a medication that contains a corticosteroid delivered in a foam formulation. SORILUX Foam is a foam formulation of calcipotriene. Both medications have been approved by the FDA for treating plaque psoriasis.

Detailed Description

This is a single center, investigator blind study. Approximately 60 qualified subjects will be enrolled into a 2 week treatment phase where they will receive 2 weeks of treatment with Olux E foam. After 2 weeks treatment, subjects with a PGA of 0 or 1 will be re randomized into maintenance phase.

Subjects that achieve PGA scores of >2 will be discontinued from the study and will not be randomized. Subjects that achieve PGA scores of 0 or 1 will enter an 8 week maintenance phase where they will be randomized on a 1:1:1 basis to one of the following treatment groups:

- Vehicle foam (BID)
- Sorilux foam (BID)
- Sorilux foam (BID on weekdays) + Olux E foam (BID on weekends)

Subjects will then attend clinic visits at week 6. At week 10 study treatment will be stopped.

The maximum duration of the study is 10 weeks and consists of a Screening/Baseline Visit (Week 0), Re randomization to maintenance phase visit (Week 2), treatment follow up visits at Weeks 6, and end of treatment visit at weeks 10.

Official Title

Olux E Foam and Sorilux Foam Combination Therapy for the Maintenance of Treatment Response in Patients With Moderate Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: vehicle foam
- Drug: calcipotriene
- Drug: calcipotriene + clobetasol propionate

Other Study ID Numbers

- OLX0112

Study Start

2013 01

Primary Completion (Actual)

2014 05

Study Completion (Actual)

2014 08

Enrollment (Actual)

63

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Clobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Clobetasol+propionate) Calcipotriene (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Calcipotriene)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Kentucky Locations

Louisville, Kentucky, United States, 40217
DermResearch, PLLC

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Outpatient, male or female subjects of any race, 18 years of age or higher. Female subjects of childbearing potential must have a negative urine pregnancy test within 7 days prior to the first dose of study drug and practice a reliable method of contraception throughout the study [Exception: Female subjects of child bearing potential who are not sexually active are not required to practice a reliable method of contraception and may be enrolled at the Investigator s discretion provided they are counseled to remain sexually inactive for the duration of the study and understand the risks involved in getting pregnant during the study.]
- Moderate plaque type psoriasis eligible for topical therapies.
- A Bod Surface Area (BSA) of 3 10%.
- Physician Global Assessment(PGA) score of 3.
- Able to understand study requirements and sign Informed Consent/Health Insurance Portability and Accountability Act forms.

Exclusion Criteria:

- Female subjects who are pregnant, breast feeding, or who are of childbearing potential and not practicing a reliable method of birth control, or male subjects planning a pregnancy with their spouse or partner while in the study.
- History of hypocalcaemia or vitamin D toxicity.
- Serious skin condition (other than psoriasis) or uncontrolled medical condition (in the opinion of the investigator).
- Topical steroids, topical immunomodulators, topical vitamin D derivatives, tar, salicylic acid, anthralin or any other topical treatment for psoriasis within 2 weeks of baseline.
- Use of any biologics within 3 months of baseline.
- Use of other systemic psoriasis treatments (ie, oral retinoids, methotrexate, cyclosporine, or other immunomodulators) within 4 weeks of baseline.
- Use of Ultraviolet B light (UVB) or oral psoralen with ultraviolet A (PUVA) within 2 weeks of baseline.
- Skin conditions (e.g. eczema) psoriasis that may interfere with evaluations of psoriasis.
- Known hypersensitivity to Sorilux Foam Ointment or any of its components.
- Known hypersensitivity to Olux E Foam or any of its components.
- Contraindications according to the Sorilux Foam or Olux E Foam package inserts.
- Current drug or alcohol abuse (Investigator opinion).
- Subject unable to commit to all the assessments required by the protocol.
- Current enrollment in another clinical study and treatment with another experimental drug or approved therapy for experimental use within 30 days prior to the Screening

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: vehicle clobetasol propionate 0.05% twice a day for two weeks; then vehicle foam twice a day every day for 8 weeks	Drug: vehicle foam • clobetasol propionate 0.05% twice a day for two weeks; then vehicle foam twice a day every day for 8 weeks
Active Comparator: calcipotriene clobetasol propionate 0.05% twice a day for two weeks; then calcipotriene 0.005% foam twice a day every day for 8 weeks x	Drug: calcipotriene • clobetasol propionate 0.05% twice a day for two weeks; then calcipotriene 0.005% foam twice a day every day for 8 weeks • Other Names: ◦ Sorilux foam 0.005% foam
Active Comparator: calcipotriene + clobetasol propionate clobetasol propionate 0.05% twice a day for two weeks; then calcipotriene 0.005% foam twice a day on weekdays for 8 weeks + clobetasol propionate 0.05% foam twice a day on weekends for 8 weeks	Drug: calcipotriene + clobetasol propionate • clobetasol propionate 0.05% twice a day for two weeks; then calcipotriene 0.005% foam twice a day on weekdays + clobetasol propionate 0.05% foam twice a day on weekends for 8 weeks • Other Names: ◦ Sorilux foam + Olux E foam

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Physician Global Assessement	Percentage of participants with clear or almost clear skin on the PGA scale. 0 = clear 1. = almost clear 2. = mild 3. = moderate 4. = severe	10 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Leon Kircik, M.D.

Collaborators

- Stiefel, a GSK Company

Investigators

- Principal Investigator: Leon H Kircik, MD, DermResearch, PLLC

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-12-06

First Submitted that Met QC Criteria
2012-12-06

First Posted (Estimated)
2012-12-07

Results Reporting Dates

Results First Submitted
2016-08-18

Results First Submitted that Met QC Criteria
2016-11-15

Results First Posted (Estimated)
2016-11-17

Study Record Updates

Last Update Submitted that met QC Criteria
2016-11-15

Last Update Posted (Estimated)
2016-11-17

Last Verified
2016-11

More Information

Terms related to this study

Keywords Provided by Leon Kircik, M.D., Derm Research, PLLC

Olux E foam
Sorilux foam

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Dermatologic Agents
Calcium Regulating Hormones and Agents
Calcium Channel Agonists
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins
Micronutrients
Bone Density Conservation Agents
Calcitriol
Clobetasol
Calcipotriene

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

A Comparison of 000-0551 Lotion Versus Vehicle Lotion in Subjects With Plaque Psoriasis (Study -304)

ClinicalTrials.gov ID NCT01871402

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2016 05 13

Study Details Tab

Study Overview

Brief Summary

This Phase 3 study has been designed to determine and compare the efficacy and safety of 000 0551 Lotion and Vehicle Lotion applied twice daily for two weeks in subjects with plaque psoriasis.

Feedback

Official Title

A Multicenter, Randomized, Double Blind, Parallel Group Comparison of 000 0551 Lotion Versus Vehicle Lotion in Subjects With Plaque Psoriasis (Study 304)

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: 000 0551 Lotion
- Drug: Vehicle Lotion

Other Study ID Numbers

- 000 0551 304

Study Start

2013 05

Primary Completion (Actual)

2013 12

Study Completion (Actual)

2013 12

Enrollment (Actual)

221

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Fremont, California, United States
Center for Dermatology Clinical Research, Inc.

San Diego, California, United States
UCSD Dermatology

Illinois Locations

Arlington Heights, Illinois, United States



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject has a clinical diagnosis of stable plaque psoriasis involving a minimum of 2% and no more than 12% affected body surface area.
- Subject has an Investigator s Global Assessment (IGA) score of at least three (moderate) at study start.
- If subject is a woman of childbearing potential, she must have a negative urine pregnancy test and agree to use an effective form of birth control for the duration of the study.

Exclusion Criteria:

- Subject has spontaneously improving or rapidly deteriorating plaque psoriasis.
- Subject has guttate, pustular, erythrodermic or other non plaque forms of psoriasis.
- Subject has used any phototherapy (including laser), photo chemotherapy or other forms of photo based therapy for the treatment of their psoriasis within 30 days prior to study start.
- Subject has used any systemic methotrexate, retinoids, systemic corticosteroids [including intralesional, intra articular, and intramuscular corticosteroids], cyclosporine or analogous products within 90 days prior to study start.
- Subject has used any systemic biologic therapy (i.e., FDA approved or experimental therapy) within five half lives of the biologic prior to study start.
- Subject had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to study start or is intending to have such exposure during the study.
- Subject has used topical body (excluding the scalp) psoriasis therapy (including coal tar, anthralin, steroids, retinoids, vitamin D analogs) within 14 days prior to study start.
- Subject has used emollients/moisturizers on areas to be treated within four hours prior to clinical evaluation at study start.
- Subject is currently using lithium or Plaquenil (hydroxychloroquine).
- Subject is currently using a beta blocking medication (e.g., propanolol) or angiotensin converting enzyme (ACE) inhibitor at a dose that has not been stabilized.
- Subject is pregnant, lactating, or is planning to become pregnant during the study.
- Subject is currently enrolled in an investigational drug or device study.
- Subject has used an investigational drug or investigational device treatment within 30 days prior to study start.
- Subject has been previously enrolled in this study and treated with a test article.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Active Arm Topical lotion, applied twice daily	Drug: 000-0551 Lotion
Placebo Comparator: Vehicle Arm Topical lotion, applied twice daily	Drug: Vehicle Lotion

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Subjects Rated a "Treatment Success" Based on the Investigator s Global Assessment (IGA)	The IGA score is a static evaluation of the overall or "average" degree of severity of a subject s disease, taking into account all of the subject s psoriatic lesions. "Treatment success" is defined as a score of 0 or 1 representing "cleared" or "almost cleared" at Day 15 with at least a two grade decrease in severity score relative to Baseline. IGA is measured on a 5-point scale, ranging from 0 (clear) to 4 (severe/very severe).	Day 15

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling, Erythema and Plaque Elevation)	A static assessment of the overall or "average" degree of severity of each of three key characteristics present within all of the subject s psoriatic lesions. "Treatment success" is defined as a score of 0 or 1 representing "cleared" or "almost cleared" at Day 15 with at least a two grade decrease in severity score relative to Baseline. Each clinical sign of psoriasis is measured on a 5-point scale, ranging from 0 (clear) to 4 (severe/very severe).	Day 15

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Subjects With IGA "Treatment	Interim analysis of IGA. "Treatment success" and IGA as defined in the primary outcome measure.	Day 8

Success" at Day 8		
Proportion of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis at Day 8	Interim analysis of clinical signs of psoriasis (scaling, erythema and plaque elevation). "Treatment success" and clinical signs as defined in the secondary outcome measure.	Day 8
Change From Baseline in Pruritus Score at Day 15	Pruritus scale will be used to assess the subjective and multidimensional experience of the subject s pruritus (itching) during the previous two weeks at Baseline and Day 15. Possible scores range from 5 (no pruritus) to 25 (most severe pruritus).	Baseline and Day 15
Change in % Body Surface Area (BSA) With Active Psoriasis at Days 8 and 15	The investigator will use the assumption that 1% BSA is approximately equal to the surface area of the subject s palm and fingers, with the fingers extended yet grouped together, creating a flat oval-like surface area.	Baseline, Day 8 and Day 15

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Therapeutics, Inc.

Collaborators

No information provided

Investigators

- Study Director: Syd Dromgoole, Ph.D., Therapeutics, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2013-06-04

First Submitted that Met QC Criteria
2013-06-04

First Posted (Estimated)
2013-06-06

Results Reporting Dates

Results First Submitted
2016-03-10

Results First Submitted that Met QC Criteria
2016-03-10

Results First Posted (Estimated)
2016-04-11

Study Record Updates

Last Update Submitted that met QC Criteria
2016-04-11

Last Update Posted (Estimated)
2016-05-13

Last Verified
2016-04

More Information

Terms related to this study

Keywords Provided by Therapeutics, Inc.

psoriasis
lotion
investigator s global assessment

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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COMPLETED

A Study to Determine the Efficacy and Safety of Halobetasol Propionate Lotion 0.05% in Subjects With Plaque Psoriasis

ClinicalTrials.gov ID **NCT01610596**

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2016 05 13

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a double blind, multicenter, vehicle controlled, parallel group comparison study to determine and compare the efficacy and safety of HBP Lotion 0.05% and Vehicle Lotion applied twice daily for two weeks in subjects with moderate to severe plaque psoriasis. Eligible subjects will be randomized (1:1) to one of two treatment groups HBP Lotion 0.05% or Vehicle Lotion. The maximum amount of test article to be applied per week should not exceed 50 grams.

Official Title

A Double blind, Randomized, Multicenter, Vehicle Controlled Parallel Group Study to Determine the Efficacy and Safety of Halobetasol Propionate Lotion 0.05% in Subjects With Plaque Psoriasis Receiving Two Weeks of Treatment

Conditions

Psoriasis Plaque Psoriasis

Intervention / Treatment

- Drug: Halobetasol Propionate Lotion 0.05%
- Drug: Placebo

Other Study ID Numbers

- 000 0551 207

Study Start

2011 11

Primary Completion (Actual)

2012 02

Study Completion (Actual)

2012 02

Enrollment (Actual)

72

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Halobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Halobetasol+propionate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

San Diego, California, United States, 92123
Therapeutics Clinical Research

Minnesota Locations

Fridley, Minnesota, United States, 55432
Minnesota Clinical Study Center

Texas Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subject is Male or non pregnant female; 18 years of age at time of Screening.
2. Subject is willing and able to give written informed consent.
3. subject is willing and able to apply the test article(s) as directed, comply with study instructions and commit to all follow up visits for the duration of the study.
4. Subject has a clinical diagnosis of stable plaque psoriasis involving a minimum of 2% and no more than approximately 10% body surface area (BSA) (excluding the face, scalp, groin, axillae and other intertriginous areas).
5. Subject has an Overall Disease Severity (ODS) score for the Treatment Area of at least three (3) at the Baseline Visit.
6. If subject is a woman of childbearing potential (WOCBP) , she must have a negative urine pregnancy test (UPT) and agree to use an effective form of birth control for the duration of the study (i.e., abstinence, stabilized on hormonal contraceptives [oral, injectable, transdermal or intravaginal] or IUD for at least three months prior to test article application, condom and a spermicidal, or diaphragm and a spermicidal). Abstinence is an acceptable form of birth control for subjects who are not sexually active. Subjects who become sexually active during the trial must agree to use an effective form of birth control for the duration of the study.

Exclusion Criteria:

1. Subject has spontaneously improving or rapidly deteriorating plaque psoriasis.
2. Subject has guttate, pustular, erythrodermic or other non plaque forms of psoriasis.
3. Subject has a physical condition which, in the investigator s opinion, might impair evaluation of plaque psoriasis, or which exposes the subject to an unacceptable risk by study participation.
4. Subject has used any phototherapy (including laser), photo chemotherapy or systemic corticosteroid therapy (such as systemic corticosteroids [including intralesional, intra articular, and intramuscular corticosteroids]) within 30 days prior to the Baseline Visit.
5. Subject has used any systemic methotrexate, retinoids, cyclosporine or analogous products within 90 days prior to the Baseline Visit.
6. Subject has used any systemic biologic therapy (i.e., FDA approved or experimental therapy) within five (5) half lives of the biologic prior to the Baseline Visit. Published or documented half life of the product provided by the commercial supplier or Sponsor should be used to establish this value.
7. Subject had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to the Baseline Visit or is intending to have such exposure during the study that is thought by the investigator likely to modify the subject s disease.
8. Subject has used topical body (excluding the scalp) psoriasis therapy including coal tar, anthralin, steroids, retinoids, vitamin D analogs (e.g., Dovonex®) within 14 days prior to the Baseline Visit.
9. Subject has used emollients/moisturizers on areas to be treated within four hours prior to clinical evaluation at the Baseline Visit.

10. Subject is currently using lithium or Plaquenil (hydroxychloroquine).
11. Subject is currently using a beta blocking medication (e.g., propanolol) or angiotensin converting enzyme (ACE) inhibitor at a dose that has not been stabilized, in the opinion of the investigator.
12. Subject has a history of sensitivity to any of the ingredients in the test article.
13. Subject is pregnant, lactating, or is planning to become pregnant during the study.
14. Subject is currently enrolled in an investigational drug or device study.
15. Subject has used an investigational drug or investigational device treatment within 30 days prior to the Baseline Visit.
16. Subject has been previously enrolled in this study and treated with a test article.
17. Subject is known to be noncompliant or is unlikely to comply with the requirements of the study protocol (e.g., due to alcoholism, drug dependency, mental incapacity) in the opinion of the investigator.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Halobetasol Propionate Lotion 0.05% Topical lotion, applied twice daily	Drug: Halobetasol Propionate Lotion 0.05% • Apply twice daily for 1-2 weeks, not to exceed 50 grams per week
Placebo Comparator: Vehicle Lotion Topical lotion, applied twice daily	Drug: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Overall Disease Severity Score (Success)	Overall disease severity (ODS) will be recorded at baseline, Day 8, and Day 15 on a 0 (clear) to 4 (severe/very severe) point scale. The primary efficacy endpoint was the percentage of subjects with ODS treatment "success" at end of treatment (Day 15). Success was defined as a grade of 0 or 1 on the ODS scale.	Day 15

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percent Body Surface Area	Changes in percent BSA with active psoriasis in the Treatment Area	Baseline, Days 8 and 15
Clinical Signs and Symptoms of Psoriasis	The proportion of subjects rated a "treatment success" for each of the clinical signs and symptoms of psoriasis: scaling, erythema, plaque elevation and pruritis. "Treatment success" is defined as a score of 0 or 1 on a five-point scale ranging from 0 = clear to 4 = severe/very severe.	Days 8 and 15
Overall Disease Severity Score (Improvement)	The proportion of subjects rated a "improved" for ODS at Day 8 and Day 15. "Improvement" is defined as at least a two (2) grade decrease in severity score relative to baseline using a five-point scale ranging from 0 = clear to 4 = severe/very severe.	Days 8 and 15

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Therapeutics, Inc.

Collaborators

No information provided

Investigators

- Study Director: Syd Dromgoole, PhD, Therapeutics, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2012-01-18

First Submitted that Met QC Criteria
2012-06-01

First Posted (Estimated)
2012-06-04

Results Reporting Dates

Results First Submitted
2016-03-10

Results First Submitted that Met QC Criteria
2016-03-10

Results First Posted (Estimated)
2016-04-11

Study Record Updates

Last Update Submitted that met QC Criteria
2016-04-11

Last Update Posted (Estimated)
2016-05-13

Last Verified

2016-04

More Information

Terms related to this study

Keywords Provided by Therapeutics, Inc.

Psoriasis
Skin Diseases
Halobetasol
Vasoconstrictor Agents
Therapeutic Uses
Pharmacologic Actions
Anti Inflammatory Agents
Physiological Effects of Drugs

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Vasoconstrictor Agents
Halobetasol

Study Documents

No study documents available

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

An Open-Label, Prospective Study to Assess the Safety and Effectiveness of Adalimumab in Patients With Moderate to Severe Plaque Psoriasis in the Russian Federation

ClinicalTrials.gov ID NCT01644396

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2014 10 01

Study Details Tab

Study Overview

Brief Summary

This is an open label study designed to establish the safety and effectiveness of adalimumab in the treatment of moderate to severe plaque psoriasis after 24 weeks of treatment.

Feedback

Detailed Description

During the treatment period, participants will receive an initial adalimumab 80 milligram (mg) subcutaneous (sc) dose, followed by adalimumab 40 mg sc every other week starting one week after initial dose. Safety and effectiveness assessments will be completed at Baseline, Week 2, Week 4, Week 8, Week 12, Week 16 and Week 24. Participants may discontinue adalimumab treatment at any time during study participation. Participants that end study participation early will have a Premature Discontinuation visit. All participants who do not initiate commercial Humira® will have a follow up phone call 70 days after the last administration of study drug to obtain information on any new or ongoing Adverse Events (AEs). The 70 day follow up phone call will not be required for any participant that initiates adalimumab therapy not supplied in the context of the clinical trial after the end of study participation.

Official Title

An Open Label, Prospective Study to Assess the Safety and Effectiveness of Adalimumab (Humira®) in Patients With Moderate to Severe Plaque Psoriasis in the Russian Federation

Conditions

Moderate to Severe Plaque Psoriasis

Intervention / Treatment

- Biological: Adalimumab

Other Study ID Numbers

- M13 279

Study Start

2012 05

Primary Completion (Actual)

2013 09

Study Completion (Actual)

2013 09

Enrollment (Actual)

50

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Russian Federation

Ekaterinburg, Russian Federation, 620076
Site Reference ID/Investigator# 67547

Kazan, Russian Federation, 420012
Site Reference ID/Investigator# 78433

Moscow, Russian Federation, 107076
Site Reference ID/Investigator# 67542

Saratov, Russian Federation, 410028
Site Reference ID/Investigator# 67546

Smolensk, Russian Federation, 214018
Site Reference ID/Investigator# 78417

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

A patient will be eligible for study participation if he/she meets the following criteria:

1. Male and female patients ≥ 18 years of age.
2. Clinical diagnosis of psoriasis for at least 6 months as determined by patient interview of his/her medical history and confirmation of diagnosis through physical examination by the investigator.
3. Stable plaque psoriasis for at least 2 months before Screening and Baseline visits as determined by patient interview of his/her medical history.
4. Moderate to severe plaque psoriasis defined by ≥ 10% Body Surface Area (BSA) involvement at the Baseline visit.
5. PASI (Psoriasis Area and Severity Index) score ≥ 10 at the Baseline visit.

Exclusion Criteria:

1. Diagnosis of erythrodermic psoriasis, pustular psoriasis, medication induced or medication exacerbated psoriasis or new onset of guttate psoriasis.
2. Diagnosis of other active skin diseases or skin infections (bacterial, fungal, or viral) that may interfere with evaluation of psoriasis.
3. Patient who cannot discontinue topical therapies for the treatment of psoriasis such as corticosteroids, vitamin D analogs, or retinoids at least 14 days prior to the Baseline (Week 0) visit and during the study. Participants are allowed to use:
    - Shampoos that contain no corticosteroid;
    - Bland (without beta or alpha hydroxy acids or containing no psoriasis treatment) emollients;
    - Low potency topical corticosteroids on the palms, soles, face, inframammary area, and groin only.
4. Patient who cannot avoid UVB (Ultraviolet B) phototherapy for at least 14 days prior to the Baseline (Week 0) visit and during the study.
5. Patient who cannot avoid PUVA (psoralen + ultraviolet A) phototherapy for at least 28 days prior to the Baseline (Week 0) visit and during the study.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Other: Adalimumab Participants received an initial adalimumab 80 mg subcutaneous dose, followed by adalimumab 40 mg subcutaneous every other week starting one week after the initial dose for up to 24 weeks.	Biological: Adalimumab • Other Names: ◦ ABT-D2E7 ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentage of Participants Achieving a Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 24	The percentage of participants with a ≥ 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline and Week 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a Physician s Global Assessment of Clear	The Physician s Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the qualified investigator s evaluation of the participant. The degree of overall lesion severity was evaluated using the following categories: • 0: No evidence of scaling, erythema, or plaque elevation, overall score of cleared; • 1: Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation, overall score of minimal; • 2: Fine scale dominates, light red coloration, mild plaque elevation, overall score of mild; • 3: Course scale dominates, moderate red coloration, moderate plaque elevation, overall score of moderate; • 4: Thick non-tenacious scale dominates, bright red coloration, marked plaque	Weeks 2, 4, 8, 12, 16 and 24

	elevation, overall score of marked; • 5: Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation, overall score of severe. The percentage of participants achieving a PGA score of clear (0) is reported.	
Percentage of Participants Achieving a Physician s Global Assessment of Clear or Minimal	The Physician s Global Assessment (PGA) is a 6-point scale used to measure the severity of disease at the time of the qualified investigator s evaluation of the participant. The degree of overall lesion severity was evaluated using the following categories: • 0: No evidence of scaling, erythema, or plaque elevation, overall score of cleared; • 1: Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation, overall score of minimal; • 2: Fine scale dominates, light red coloration, mild plaque elevation, overall score of mild; • 3: Course scale dominates, moderate red coloration, moderate plaque elevation, overall score of moderate; • 4: Thick non-tenacious scale dominates, bright red coloration, marked plaque elevation, overall score of marked; • 5: Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation, overall score of severe. The percentage of participants achieving a PGA score of clear (0) or minimal (1) is reported.	Weeks 2, 4, 8, 12, 16 and 24
Percentage of Participants Achieving a One	The PGA is a 6-point scale used to measure the severity of disease at the time of the qualified investigator s evaluation of the participant. The	Baseline and Weeks

Grade Improvement in Physicians Global Assessment (PGA)	degree of overall lesion severity was evaluated using the following categories: • 0: No evidence of scaling, erythema, or plaque elevation, overall score of cleared; • 1: Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation, overall score of minimal; • 2: Fine scale dominates, light red coloration, mild plaque elevation, overall score of mild; • 3: Course scale dominates, moderate red coloration, moderate plaque elevation, overall score of moderate; • 4: Thick non-tenacious scale dominates, bright red coloration, marked plaque elevation, overall score of marked; • 5: Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation, overall score of severe. The percentage of participants achieving a shift from Baseline to a less severe category is reported.	2, 4, 8, 12, 16 and 24
Percentage of Participants Achieving a PASI 50 Response	The percentage of participants with a ≥ 50% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline and Weeks 2, 4, 8, 12, 16, and 24

Percentage of Participants Achieving a PASI 75 Response	The percentage of participants with a ≥ 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline and Weeks 2, 4, 8, 12, and 16
Percentage of Participants Achieving a PASI 90 Response	The percentage of participants with a ≥ 90% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline and Weeks 2, 4, 8, 12, 16, and 24
Percentage of Participants Achieving a PASI 100 Response	The percentage of participants with a 100% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI	Baseline and Weeks 2, 4, 8, 12, 16, and 24

	scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score	PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease. Change from Baseline is presented as a percentage of the Baseline value: Post-baseline value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Weeks 2, 4, 8, 12, 16, and 24
Percent Change From Baseline in Dermatology Life Quality Index (DLQI)	The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment related feelings. Participants answer 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is 0 to 30. A score of 21 to 30 means an extremely large effect on the participant s life whereas 0-1 means that the disease has no effect at all. Change from Baseline is presented as a percentage of the Baseline value: Post-baseline value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Weeks 8, 12, and 24

Percent Change From Baseline in Nail Psoriasis Severity Index (NAPSI)	NAPSI grades nails for both nail matrix psoriasis and nail bed psoriasis. The most affected fingernail was determined at Baseline and used for the analysis. Nail matrix psoriasis consists of any of the following: pitting, leukonychia, red spots in the lunula, or nail plate crumbling. Nail bed psoriasis is the presence or absence of onycholysis, splinter hemorrhages, oil drop (salman patch) discoloration or nail bed hyperkeratosis. Scoring for each is based on the following scale: • 0 = none; • 1 = present in 1/4 nail quadrants; • 2 = present in 2/4 nail quadrants; • 3 = present in 3/4 nail quadrants; • 4 = present in 4/4 nail quadrants. The sum of these two scores is the total score for the nail, and ranges from 0 (no nail psoriasis) to 8 (psoriasis in 4/4 nail quadrants). Change from Baseline is presented as a percentage of the Baseline value, calculated as: Week 24 value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Week 24

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Hemoglobin	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in	Safety variables included laboratory data, vital signs and adverse events. The	Baseline and Week

Hematocrit	hematocrit measures the volume of red blood cells compared to the total blood volume (red blood cells and plasma).	24 (or Early Termination Visit)
Change From Baseline in Red Blood Cell Count	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Blood Cell Counts	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Erythrocyte Sedimentation Rate	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Alanine Aminotransferase	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Aspartate Aminotransferase	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Alkaline Phosphatase	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)

Change From Baseline in Total Bilirubin	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Creatinine	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Blood Urea Nitrogen (BUN)	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Uric Acid	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Inorganic Phosphate	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Calcium, Sodium and Potassium	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)

Change From Baseline in Glucose	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Albumin	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Total Protein	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Cholesterol	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Triglycerides	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in High Sensitivity C-reactive Protein (hsCRP)	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)

Change From Baseline in Urine pH	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Urine Specific Gravity	Safety variables included laboratory data, vital signs and adverse events. Specific gravity is a measure of the amount of material dissolved in the urine. Specific gravity is the ratio of the density (mass of a unit volume) of a substance to the density (mass of the same unit volume) of a reference substance.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Blood Pressure	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Pulse	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Respiratory Rate	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Change From Baseline in Weight	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)

Change From Baseline in Body Temperature	Safety variables included laboratory data, vital signs and adverse events.	Baseline and Week 24 (or Early Termination Visit)
Number of Participants With Adverse Events (AEs)	An AE is any untoward medical occurrence, which does not necessarily have a causal relationship with treatment. The investigator rated the severity of each AE as either: Mild: The AE is transient and easily tolerated; Moderate: The AE causes the participant discomfort and interrupts usual activities. Severe: The AE causes considerable interference with usual activities and may be incapacitating or life-threatening. A serious adverse event (SAE) is an AE that results in death, is life-threatening, results in or prolongs hospitalization, results in congenital anomaly, persistent or significant disability/incapacity, spontaneous or elective abortion, or requires intervention to prevent a serious outcome. Drug-related AEs are those assessed by the investigator as either probably or possibly related. Other malignancy excludes lymphoma, hepatosplenic T-cell lymphoma (HSTCL), leukemia, non-melanoma skin cancer (NMSC), and melanoma.	From the first dose of study drug until 70 days after the last dose (up to 33 weeks).

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

No information provided

Investigators

- Study Director: Martin Okun, MD, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2012-05-07

First Submitted that Met QC Criteria

2012-07-17

First Posted (Estimated)
2012-07-19

Results Reporting Dates

Results First Submitted
2014-09-09

Results First Submitted that Met QC Criteria
2014-09-09

Results First Posted (Estimated)
2014-09-17

Study Record Updates

Last Update Submitted that met QC Criteria
2014-09-22

Last Update Posted (Estimated)
2014-10-01

Last Verified
2014-09

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Moderate to Severe Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related Info (http://rxabbvie.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study of the Safety and Effectiveness of Ustekinumab (Stelara) in Chinese Patients With Psoriasis

ClinicalTrials.gov ID **NCT01008995**

Sponsor Centocor, Inc.

Information provided by Centocor, Inc. (Responsible Party)

Last Update Posted 2013 11 11

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy (good or bad effects) and safety of ustekinumab in the treatment of patients with moderate to severe psoriasis in China.

Feedback

Detailed Description

In this study, 220 patients will be divided into two groups randomly (by chance), like flipping a coin. Each group will receive a different treatment. The results for each group are compared to each other. There are 2 treatment groups in this study, Group 1 and Group 2. Group 1 will receive placebo at Weeks 0 and 4, ustekinumab 45 mg at Weeks 12 and 16. Group 2 will receive ustekinumab 45 mg at Weeks 0, 4, and 16 and placebo at Week 12. All patients in the study will eventually receive ustekinumab after Week 12. The patients will be in the study for about 36 weeks, with study visit approximately 10 times. Effectiveness evaluations will be conducted throughout the study and include the Psoriasis Area and Severity Index (PASI), Physicians Global Assessment (PGA) and Dermatology Life Quality Index (DLQI). Safety assessments will also be performed throughout the study and include obtaining and evaluating laboratory tests, vital signs (e.g., blood pressure) and the occurrence and severity of adverse events. GROUP 1: Placebo at Weeks 0 and 4, ustekinumab 45 mg at Weeks 12 and 16. GROUP 2: Ustekinumab 45 mg at Weeks 0, 4, and 16. Placebo at Week 12

Official Title

A Phase 3, Multicenter, Randomized, Double blind, Placebo controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Chinese Subjects With Moderate to Severe Plaque type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: placebo
- Drug: ustekinumab
- Drug: placebo
- Drug: ustekinumab

Other Study ID Numbers

- CR016318
- C0743T23 (Other Identifier) (OTHER: Centocor)
- CR016318 (Other Identifier) (OTHER: Centocor)

Study Start

2009 10

Primary Completion (Actual)

2011 07

Study Completion (Actual)

2011 07

Enrollment (Actual)

322

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Ustekinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ustekinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

China

- Beijing, China
- Chongqing, China
- Dalian, China

Guangzhou, China

Hangzhou, China

Nanjing, China

Shanghai, China

Shenyang, China

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Must be of Chinese ancestry
- Have had a diagnosis of plaque type psoriasis at least 6 months pr or to study start
- Have plaque type psoriasis covering at least 10% of total BSA at screening and at the time of study start
- Have a Psoriasis Area and Severity Index (PASI) score of 12 or greater at study start
- Must be candidates for phototherapy or systemic treatment of psoriasis (either naive or history of previous treatment)

Exclusion Criteria:

- Currently have nonplaque forms of psoriasis
- Have current drug induced psoriasis
- Have used any investigational drug within the previous 4 weeks
- Have used any biologic within the previous 3 months
- Be known to be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), or syphilis

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 001 placebo Subcutaneous injection at Week 0 and 4,ustekinumab 45 mg subcutaneous injection at Week 12 and 16	Drug: placebo • Subcutaneous injection at Week 0 and 4 Drug: ustekinumab • 45 mg subcutaneous injection at Week 12 and 16
Experimental: 002 placebo Subcutaneous injection at Week 12,ustekinumab 45 mg subcutaneous injection at Week 0 4 and 16	Drug: placebo • Subcutaneous injection at Week 12 Drug: ustekinumab • 45 mg subcutaneous injection at Week 0, 4 and 16

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Number of Patients Who Achieved at	Scores could range from 0 (mild) to 72 (severe).	Baseline (Week

Least a 75% Improvement in PASI (Psoriasis Area and Severity Index) From Baseline at Week 12.		0) to Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Number of Patients With a Physicians Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12		Week 12
The Change in Dermatology Life Quality Index (DLQI) From Baseline at Week 12.	Scores could range from 0 to 30. A lower DLQI score represents better quality of life.	Baseline (Week 0) to Week 12

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Centocor, Inc.

Collaborators

No information provided

Investigators

- Study Director: Centocor, Inc. Clinical Trial, Centocor, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2009-11-05

First Submitted that Met QC Criteria
2009-11-05

First Posted (Estimated)
2009-11-06

Results Reporting Dates

Results First Submitted
2012-08-15

Results First Submitted that Met QC Criteria
2012-08-15

Results First Posted (Estimated)

2012-09-14

Study Record Updates

Last Update Submitted that met QC Criteria

2013-10-17

Last Update Posted (Estimated)

2013-11-11

Last Verified

2013-10

More Information

Terms related to this study

Keywords Provided by Centocor, Inc.

psoriasis
asian patients
Chinese
ustekinumab
CNTO 1275
Stelara

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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COMPLETED

A Study Comparing Tazarotene Cream 0.05% to TAZORAC® (Tazarotene) Cream 0.05% and Both to a Placebo Control in the Treatment of Plaque Psoriasis

ClinicalTrials.gov ID **NCT02886702**

Sponsor Fougera Pharmaceuticals Inc.

Information provided by Fougera Pharmaceuticals Inc. (Responsible Party)

Last Update Posted 2018 08 29

Study Details Tab

Study Overview

Brief Summary

Feedback

A Multi Center, Double Blind, Randomized, Vehicle Controlled, Parallel Group Study Comparing Tazarotene Cream 0.05% to TAZORAC® (tazarotene) Cream 0.05% and Both Active Treatments to a Vehicle Control in the Treatment of Stable Plaque Psoriasis

Official Title

A Multi Center, Double Blind, Randomized, Vehicle Controlled, Parallel Group Study Comparing Tazarotene Cream 0.05% to TAZORAC® (Tazarotene) Cream 0.05% and Both Active Treatments to a Vehicle Control in the Treatment of Stable Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Tazarotene Cream 0.05%
- Drug: TAZORAC® (tazarotene) Cream 0.05%
- Drug: Placebo

Other Study ID Numbers

- 0453 01 01
- 0453 (Other Identifier) (OTHER: Fougera Pharmaceuticals Inc.)

Study Start (Actual)

2016 09 19

Primary Completion (Actual)

2017 08 02

Study Completion (Actual)

2017 08 02

Enrollment (Actual)

855

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Tazarotene (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Tazarotene)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arizona Locations

Phoenix, Arizona, United States, 85018
Fougera Investigational Site

Arkansas Locations

Hot Springs, Arkansas, United States, 71913
Fougera Investigational Site

California Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have a definite clinical diagnosis of stable (at least 6 months) plaque psoriasis, involving at least 2% and no more than 20% of the body surface area (BSA) (not including the scalp and intertriginous areas)
- Have a minimum plaque elevation at the target lesion site of at least moderate severity (grade ≥ 3 on the Psoriasis Area Severity Index [PASI]). The most severe lesion at baseline should be identified as the target lesion
- Have an Investigator s Global Assessment (IGA) of disease severity of at least moderate (score ≥ 3) as an overall assessment of all lesions to be treated.

Exclusion Criteria:

- A female subject who is pregnant, nursing, planning a pregnancy, or does not agree to use an acceptable form of birth control within the study participation period
- Have a current diagnosis of unstable forms of psoriasis in the treatment area, including pustular, guttate, exfoliative or erythrodermic psoriasis
- Have a history of psoriasis unresponsive to topical treatments

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Test Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)	Drug: Tazarotene Cream 0.05% • Tazarotene Cream 0.05% to cover only the lesions with a thin film. • Other Names: ◦ Tazarotene
Active Comparator: Reference TAZORAC® (tazarotene) Cream 0.05% (Allergan, Inc.)	Drug: TAZORAC® (tazarotene) Cream 0.05% • TAZORAC® (tazarotene) Cream 0.05% to cover only the lesions with a thin film. • Other Names: ◦ Tazarotene
Placebo Comparator: Placebo Placebo (Vehicle of test product) (Fougera Pharmaceuticals Inc.)	Drug: Placebo • Placebo (vehicle of the test product) to cover only the lesions with a thin film. • Other Names: ◦ Vehicle

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Treatment Success Assessed by IGA	Proportion of subjects with treatment success (defined as none, minimal or mild disease, a score of 0, 1 or 2 within the treatment area) on the "Investigator s Global Assessment of Disease Severity" (IGA) at the Week 12 visit (Day 85 ± 4 days, End of Study).	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Disease Severity None or Minimal on IGA	Proportion of subjects with none or minimal disease, a score of 0 or 1 on the IGA at the Week 12 visit (Day 85 ± 4 days, End of Study).	Week 12
Target Site Plaque Elevation, Scaling and Erythema Scores of Less Than or Equal to 1 on the PASI	Proportion of subjects with target site plaque elevation, scaling and erythema scores of less than or equal to 1 (Clear or Almost Clear) on the Psoriasis Area Severity Index (PASI) at the Week 12 visit (Day 85 ± 4 days, End of Study).	Week 12

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Fougera Pharmaceuticals Inc.

Collaborators

No information provided

Investigators

- Study Director: Angela C. Kaplan, Fougera Pharmaceuticals Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2016-08-29

First Submitted that Met QC Criteria
2016-08-29

First Posted (Estimated)
2016-09-01

Results Reporting Dates

Results First Submitted
2018-07-30

Results First Submitted that Met QC Criteria
2018-07-30

Results First Posted ⓘ
2018-08-29

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ
2018-07-30

Last Update Posted ⓘ
2018-08-29

Last Verified ⓘ
2018-07

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Keratolytic Agents
Vitamin B Complex
Vitamins
Micronutrients
Physiological Effects of Drugs
Nicotinic Acids
Tazarotene

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Study Documents

- Study Protocol (https://storage.googleapis.com/ctgov2 large docs/02/NCT02886702/Prot_000.pdf) [PDF, 0.79MB, 2016 12 22]
- Statistical Analysis Plan (https://storage.googleapis.com/ctgov2 large docs/02/NCT02886702/SAP_001.pdf) [PDF, 0.79MB, 2017 04 26]

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Record 1 of 1

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COMPLETED

Ammonium Lactate Lotion 12% (Lac-hydrin®) and Halobetasol Propionate Ointment 0.05% (Ultravate®) in the Treatment and Maintenance of Psoriasis

ClinicalTrials.gov ID NCT01111123

Sponsor Icahn School of Medicine at Mount Sinai

Information provided by Icahn School of Medicine at Mount Sinai (Responsible Party)

Last Update Posted 2016 06 24

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine whether the combinational use of ammonium lactate lotion 12% (Lac Hydrin) and halobetasol propionate ointment 0.05% (Ultravate) is safe and effective in the initial treatment and long term maintenance of psoriasis. Patients will use both medications

Feedback

continuously for two weeks and those who obtain a good improvement based on investigator clinical assessments will be randomized to Lac Hydrin lotion twice daily every day with placebo ointment or Ultravate ointment twice daily on weekends only for up to 24 more weeks.

Detailed Description

This is a randomized, double blind, placebo controlled, clinical trial assessing the efficacy of Ultravate ointment in combination with Lac Hydrin lotion in the treatment of plaque psoriasis. In the first phase, patients will be treated for two weeks with combination therapy using Ultravate ointment twice daily along with Lac Hydrin lotion twice daily. After two weeks, psoriasis plaques will be evaluated to test treatment efficacy. Those patients with a significant clinical improvement per investigator clinical assessments, will be randomized in a 1:1 fashion into a maintenance phase and receive Lac Hydrin lotion twice daily everyday with placebo ointment or Ultravate ointment twice daily on weekends only. Continuous use of Ultravate ointment will be discontinued following two weeks of treatment in compliance with its FDA indication. Patients will be evaluated every 4 weeks (monthly) through the maintenance phase. The purpose of this second phase of the study is to investigate whether use of Ultravate on weekends only can minimize risk of plaque recurrence, maximize duration of therapeutic effect, while limiting the need for the use of long term continuous topical corticosteroid treatment. As well, the second phase of the study is to investigate whether twice daily Lac Hydrin lotion has an impact in maximizing the duration of therapeutic effect as well as minimizing local cutaneous side effects such as skin atrophy and telangiectasia. Part of this clinical study consists of the use of patient and self assessment questionnaires and the use of non identifying digital photography of target lesions. The hypothesis is that Ultravate ointment on weekends only will be statistically more efficacious at maintaining an excellent initial clinical response and its combination with Lac Hydrin lotion will help to minimize any local cutaneous side effects as well as enhance its therapeutic effect.

Official Title

A Randomized, Double blind Study to Evaluate the Efficacy of Ammonium Lactate Lotion 12% (Lac hydrin®) and Halobetasol Propionate Ointment 0.05% (Ultravate®) in the Treatment and Maintenance of Psoriasis.

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Lac Hydrin lotion (ammonium lactate lotion 12%) ; Ultravate ointment (halobetasol propionate ointment 0.05%)
- Drug: Lac Hydrin lotion (ammonium lactate lotion 12%); placebo ointment

Other Study ID Numbers

- GCO 08 1061 0001 01 DE

Study Start

2009 01

Primary Completion (Actual)

2010 03

Study Completion (Actual)

2010 03

Enrollment (Actual)

55

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Lactic acid (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Lactic+acid) Ammonium lactate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ammonium+lactate) Halobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Halobetasol+propionate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

New York Locations

New York, New York, United States, 10029
Icahn School of Medicine at Mount Sinai,
Department of Dermatology

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Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subjects must be at least 18 years of age and in good general healt as confirmed by a medical history.
- Females of childbearing potential must have a negative urine pregnancy test on Day 1 and must agree to use adequate birth control methods during the entire study.
- A clear diagnosis of plaque psoriasis must have been previously established and the disease must have been present at least 6 months.
- Subjects must have lesions suitable for evaluating response to test agents. The severity of the disease at Day 1 must be rated at least 2 (Mild) for each of the key psoriasis characteristics (scaling, erythema, and plaque elevation).
- Subjects must be able to understand the requirements of the study, abide by the restrictions, and return for the required examinations. All subject must sign the statement of informed consent approved for the study.

Exclusion Criteria:

- Subjects who are pregnant (determi ed from a urine pregnancy test on Day 1).
- Subjects who are nursing.
- Subjects with known hypersensitivity to any components of the test medication.
- Subjects requiring any other medication (topical or systemic) that may affect the course of the disease during the study period (e.g. antibiotics, sedating antihistamines).
- Subjects using biologics or any other systemic treatment for psoriasis within 12 weeks of entering the study.
- Subjects using systemic corticosteroids within 28 days of entering the study; subjects using topical corticosteroids or other topical therapies (other than emollients) at any location on the body within 1 week of entering the study.
- Subjects with overt pre existing telangiectasia or skin atrophy at intended treatment sites.
- Subjects who are using any medication or has any disease which in the judgment of the investigator will interfere with the conduct or interpretation of the study.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: 1 Lac-Hydrin lotion twice daily everyday + Ultravate ointment twice daily on weekends only	Drug: Lac-Hydrin lotion (ammonium lactate lotion 12%) ; Ultravate ointment (halobetasol propionate ointment 0.05%) • Steroid on weekends only group
Placebo Comparator: 2 Lac-Hydrin lotion twice daily everyday + placebo ointment twice daily on weekends only	Drug: Lac-Hydrin lotion (ammonium lactate lotion 12%); placebo ointment • Placebo on weekends only group

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Physical Global Assessment	Physician global assessment (PGA) score - the physicians impression of the disease at a single time point rated as: 0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe, and 5=very severe.	During the maintenance phase, from 2 weeks up to 26 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Signs of Psoriasis, Atrophy or Telangiectasis	Signs of psoriasis (erythema, induration, and scale) - physicians assessment of the severity of each of the three key characteristics of psoriatic lesions rated as: 0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe, and 5=very severe, combined into one score.	During the maintenance phase, from 2 weeks up to 26 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Icahn School of Medicine at Mount Sinai

Collaborators

No information provided

Investigators

- Principal Investigator: Jason J Emer, MD, Icahn School of Medicine at Mount Sinai

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2010-04-22

First Submitted that Met QC Criteria
2010-04-23

First Posted (Estimated)
2010-04-27

Results Reporting Dates

Results First Submitted
2011-06-15

Results First Submitted that Met QC Criteria
2016-05-25

Results First Posted (Estimated)
2016-06-24

Study Record Updates

Last Update Submitted that met QC Criteria
2016-05-25

Last Update Posted (Estimated)
2016-06-24

Last Verified
2016-05

More Information

Terms related to this study

Keywords Provided by Icahn School of Medicine at Mount Sinai

plaque psoriasis
lac hydrin
ammonium lactate
Ultravate
halobetasol propionate
weekend only application
topical therapy
topical corticosteroid
class I steroid

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Vasoconstrictor Agents
Halobetasol

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

A Multicentre, Open Label Phase IIIb/IV Study of Subcutaneously Administered Raptiva in the Treatment of Adult Subjects With Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT00287118**

Sponsor Merck KGaA, Darmstadt, Germany

Information provided by Merck KGaA, Darmstadt, Germany (Responsible Party)

Last Update Posted 2018 04 03

Study Details Tab

Study Overview

Brief Summary

An open label, multi center study to establish psoriasis control of moderate to severe plaque psoriasis with Raptiva therapy administered subcutaneously for 24 weeks.

Feedback

Official Title

A Multicentre, Open Label Phase IIIb/IV Study of Subcutaneously Administered Raptiva in the Treatment of Adult Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Candidates for Systemic Therapy for Psoriasis Psoriasis

Intervention / Treatment

- Drug: Efalizumab

Other Study ID Numbers

- 25161
- CONTROL I Study

Study Start (Actual)

2004 10 27

Primary Completion (Actual)

2006 05 30

Study Completion (Actual)

2006 05 30

Enrollment (Actual)

189

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Switzerland

Geneva, Switzerland
Medical Information Switzerland

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- A) In the opinion of the investigator, candidate for systemic therapy for psoriasis could include:
- Patients with moderate to severe plaque psoriasis defined by Psoriasis Area and Severity Index (PASI) less than (>) 10 and body surface area (BSA) greater than (>) 10
- Patients with the following may also be deemed to require systemic therapy in the judgement of the physician:
- Severe psychosocial disability (in the judgement of the physician), or
- Nail psoriasis, or
- Scalp psoriasis, or
- Palmar plantar psoriasis etc OR
- B) Subjects who have completed the CLEAR study investigational medicinal product (IMP) 24011 (NCT00256139) and who wish to continue Raptiva (efalizumab) therapy.
- Body weight of 120 kg
- 18 to 75 years old
- For women of childbearing potential and for men whose partner can become pregnant, use of an acceptable method of contraception to prevent pregnancy and agreement to continue to practice an acceptable method of contraception for the duration of their participation in the study up to 3 months after the last dose of Raptiva
- Willingness to hold sun exposure reasonably constant and to avoid use of tanning booths or other ultraviolet (UV) light sources during the study
- Agreement to participate in the study
- Signed informed consent
- Discontinuation of any systemic psoriasis treatment prior to commencement of the study drug. No washout period is required for these agents prior to starting study and receiving first dose of study drug (Raptiva)
- Discontinuation of all biologic agents (other than Raptiva) 3 months prior to receiving first dose of study drug (Raptiva)
- Discontinuation of Psoralen ultraviolet light A (PUVA), Ultraviolet light B (UVB) treatment 28 days prior to commencement of receiving first dose of study drug.
- Discontinuation of any investigational drug or treatment 3 months prior to study Day 0 or as per washout requirements from previous protocol
- No vaccinations (e.g., tetanus, booster, influenza vaccine) at least 14 days prior to first dose of study drug
- Treatment regimens of b blockers, Angiotensin converting enzyme (ACE) inhibitors, antimalarial drugs, quinidine, interferon, or lithium stable for at least 28 days prior to first dose of study drug

Exclusion Criteria:

- Guttate, erythrodermic, or pustular psoriasis as sole or predominant form of psoriasis
- Active rebound of psoriasis during or following discontinuation of the previous Raptiva treatment(PASI >125% from baseline and/or new predominant morphology of

psoriasis) when reason was adverse event or lack of efficacy of Raptiva. If it was due to another non drug reason (vaccination, or infection) then the patient can be included in this study.

- History of severe allergic or anaphylactic reactions to humanised monoclonal antibodies
- History of or ongoing uncontrolled bacterial, viral, fungal, or atypical mycobacterial infection
- History of opportunistic infections (e.g., systemic fungal infections, parasites)
- Seropositivity for human immunodeficiency virus (HIV). Patients will undergo mandatory testing at screening. Patients who are positive for HIV will be excluded.
- Pregnancy or lactation
- White blood cell (WBC) count <4000 per Liter (L) or >14,000/L
- Patient with a history of clinically significant thrombocytopenia, bleeding disorders or a platelet count < 00,000 cells/L
- Seropositivity for hepatitis B or C virus Patients will undergo testing at screening. Patients who are positive for hepatitis B antigen or hepatitis C antibody will be excluded.
- Hepatic enzymes >3 times the upper limit of normal
- History of active tuberculosis (TB) or currently undergoing treatment for TB within one year prior to study Day 0. Chest X ray (within 3 months prior to Study Day 0) is required for high risk patients. Patients with a positive chest X ray will be excluded.
- Presence of malignancy within the past 5 years, including lymphoproliferative disorders. Patients with a history of fully resolved basal cell or squamous cell skin cancer may be enrolled.
- Diagnosis of hepatic cirrhosis, regardless of cause or severity
- Serum creatinine >2 times the upper limit of normal
- Hospital admission for cardiac disease, stroke, or pulmonary disease within the last year
- History of substance abuse within the last 5 years
- Any medical condition that, in the judgment of the investigator, would jeopardize the patient s safety following exposure to study drug

Ages Eligible for Study

17 Years to 75 Years (Child, Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Efalizumab	Drug: Efalizumab • Subjects will receive a conditioning dose of 0.7 milligram per kilogram (mg/kg) efalizumab subcutaneously on study Day 0 followed by 1.0 mg/kg efalizumab subcutaneously once a week for 23 weeks. • Other Names: ◦ Raptiva

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects With Physician s Global Assessment (PGA) Ratings	The PGA rating was used to assess the global response of all psoriatic lesions by comparing subject s present condition to baseline photographs or body diagrams. The response was classified as Cleared: 100% improvement of all clinical signs and symptoms compared to	Week 24

of "Excellent" or "Cleared" at Week 24	baseline; Excellent: 75% to 99% improvement of all signs and symptoms compared to baseline; Good: 50% to 74% improvement of signs and symptoms compared to baseline; Fair: 25% to 49% improvement of signs and symptoms compared to baseline; Slight: 1% to 24% improvement of signs and symptoms compared to baseline; Unchanged: Clinical signs and symptoms unchanged from baseline and Worse: Clinical signs and symptoms deteriorated from baseline.	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck KGaA, Darmstadt, Germany

Collaborators

No information provided

Investigators

- Study Director: Medical Responsible, Merck KGaA, Darmstadt, Germany

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2006-02-02

First Submitted that Met QC Criteria
2006-02-02

First Posted (Estimated)
2006-02-06

Results Reporting Dates

Results First Submitted
2017-08-29

Results First Submitted that Met QC Criteria
2017-08-29

Results First Posted
2018-04-03

Study Record Updates

Last Update Submitted that met QC Criteria
2017-08-29

Last Update Posted
2018-04-03

Last Verified
2017-08

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Efficacy and Safety of GTx-024 in Patients With Estrogen Receptor (ER)+/ Androgen Receptor (AR)+ Breast Cancer

ClinicalTrials.gov ID **NCT02463032**

Sponsor GTx

Information provided by GTx (Responsible Party)

Last Update Posted 2020 12 09

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine if GTx 024 at different dosages (9 mg or 18 mg) is effective and safe in the treatment of patients with metastatic or locally advanced Estrogen Receptor (ER)+ and Androgen Receptor (AR)+ breast cancer in postmenopausal women.

Feedback

Official Title

A Phase 2 Open Label, Multi Center, Multinational, Randomized, Parallel Design Study Investigating The Efficacy and Safety Of GTx 024 On Metastatic or Locally Advanced ER+/AR+ Breast Cancer (BC) in Postmenopausal Women

Conditions

ER+ and AR+ Breast Cancer

Intervention / Treatment

- Drug: GTx 024

Other Study ID Numbers

- G200802

Study Start (Actual)

2015 08

Primary Completion (Actual)

2019 03

Study Completion (Actual)

2019 03

Enrollment (Actual)

136

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Spinal and bulbar muscular atrophy (https://medlineplus.gov/genetics/condition/spinal and bulbar muscular atrophy) Breast cancer (https://medlineplus.gov/genetics/condition/breast cancer)

MedlinePlus (https://medlineplus.gov/) related topics: Breast Cancer (https://medlineplus.gov/breastcancer.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Kennedy Disease (https://rarediseases.info.nih.gov/diseases/6818/kennedy_disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Enobosarm (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Enobosarm)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Florida Locations

Fort Lauderdale, Florida, United States, 33308
Holy Cross Hospital

Massachusetts Locations

Boston, Massachusetts, United States, 02215
Dana Farber Cancer Institute

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Adult women (≥ 18 years of age) with metastatic or recurrent locally advanced BC, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression.
    - Women must have received ≥ 1 prior hormonal treatment(s) in the metastatic or adjuvant setting. If the most recent hormonal treatment was in the metastatic setting, duration of response (tumor regression or stabilization of disease) to this specific course of therapy must be ≥ 6 months. If the most recent hormonal treatment was in the adjuvant setting, duration of response (disease free) to this specific course of therapy must be ≥ 3 years
- Histological or cytological confirmation of ER+ BC as assessed by a local laboratory using slides, paraffin blocks, or paraffin sample or by medical history: ER+ (confirmed as ER expression more than or equal to 1% positive tumor nuclei)
- Human epidermal growth factor receptor 2 (HER2) negative tumor by local laboratory testing (immunohistochemistry [IHC] 0, 1+ regardless of fluorescence in situ hybridization [FISH] ratio; IHC 2+ with FISH ratio lower than 2.0 or HER2 gene copy less than 6.0; FISH ratio of 0, indicating gene deletion, when positive and negative in situ hybridization [ISH] controls are present)
- Availability of paraffin embedded or formalin fixed tumor tissue; OR, a minimum of 10 and up to 20 slides of archived tumor tissue or new biopsy, if archived tissue is unavailable for central laboratory confirmation of AR status and molecular subtyping. Metastatic tumor tissue is preferred when possible.
- Postmenopausal women. Postmenopausal status is defined by the National Comprehensive Cancer Network as either:
    - Age ≥ 55 years and one year or more of amenorrhea
    - Age < 55 years and one year or more of amenorrhea, with an estradiol assay < 20 pg/mL
    - Age < 55 years and surgical menopause with bilateral oophorectomy a. Note: Ovarian radiation or treatment with a luteinizing hormone releasing hormone (LH RH) agonist (goserelin acetate or leuprolide acetate) is not permitted for induction of ovarian suppression at the time of screening. Long term use (>6 months prior to screening) is permitted
- Radiological or clinical evidence (bone scan, computerized tomography [CT], and magnetic resonance Imaging [MRI]) of recurrence or progression within 30 days before randomization
- Subject must have either measurable disease or bone only non measurable disease, according to RECIST1.1
- Adequate organ function as shown by:
    - Absolute neutrophil count (ANC) ≥ 1,500 cells/mm3
    - Platelet count ≥ 100,000 cells/mm3
    - Hemoglobin (Hgb) ≥ 9.0 g/dL

  - Serum aspartate aminotransferase (AST) and alanine transaminase (ALT) ≤ 2.5 upper limit of the normal range (ULN) (or ≤ 5 if hepatic metastases are present)
  - Total serum bilirubin ≤ 2.0 × ULN (unless the subject has documented Gilbert Syndrome)
  - Alkaline phosphatase levels ≤ 2.5 × ULN (≤ 5 × ULN in subjects with liver metastasis)
  - Serum creatinine ≤ 2.0 mg/dL or 177 µmol/L
  - International normalized ratio (INR), activated partial thromboplastin (aPTT), or partial thromboplastin time (PTT) < 1.5 × ULN (unless on anticoagulant treatment at screening)
- Subject has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Subjects with bone metastases should be treated with intravenous bisphosphonates or subcutaneous denosumab (or investigator preferred standard of care) prior to and/or during the trial, unless there is a contraindication or subject intolerance to these therapies. For patients who are normocalcemic, therapy can be initiated at the time the patient initiates study drug
- Subject is able to swallow capsules
- Able and willing to give voluntary, written and signed informed consent before any screening procedure and according to local guidelines

Exclusion Criteria:

- Previously received > 1 course of chemotherapy (not including immunotherapies or targeted therapies) for the treatment of metastatic

  a. Note: Subjects may have received 1 course of chemotherapy prior to surgery for the treatment of locally advanced disease and 1 course of chemotherapy for the treatment of metastatic BC; however, if surgery could not be performed, this will count as the 1 chemotherapy course allowed prior to study
- Known hypersensitivity to any of the GTx 024 components or subjects previously received treatment with SARM
- Subjects with radiographic evidence of central nervous system (CNS) metastases as assessed by CT or MRI that are not well controlled (symptomatic or requiring control with continuous corticosteroid therapy [e.g., dexamethasone])

  a. Note: Subjects with CNS metastases are permitted to participate in the study if the CNS metastases are medically well controlled and stable for at least 28 days after receiving local therapy (irradiation, surgery, etc.)
- Radiotherapy within 14 days prior to randomization except in case of localized radiotherapy for analgesic purpose or for lytic lesions at risk of fracture, which can then be completed within 7 days prior to randomization. Subjects must have recovered from radiotherapy toxicities prior to randomization
- Currently receiving hormone replacement therapy, unless discontinued prior to screening
- Subjects positive for Human Immunodeficiency Virus (HIV)
- Subject has a concomitant medical condition that precludes adequate study treatment compliance or assessment, or increases subject risk, in the opinion of the Investigator, such as but not limited to:

    - Myocardial infarction or arterial thromboembolic events within 6 months prior to Baseline or severe or unstable angina, New York Heart Association (NYHA) Class III or IV disease, or a QTcB (corrected according to Bazett s formula) interval > 470 msec
    - Serious uncontrolled cardiac arrhythmia grade II or higher according to NYHA
    - Uncontrolled hypertension (systolic > 150 and/or diastolic > 100 mm Hg)
    - Acute and chronic, active infectious disorders and non malignant medical illnesses that are uncontrolled or whose control may be jeopardized by the complications of this study therapy
    - Impairment of gastrointestinal function or gastrointestinal disease that may significantly alter the absorption of study drugs (e.g., ulcerative disease, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome)
    - Another active cancer (excluding adequately treated basal cell carcinoma or cervical intraepithelial neoplasia [CIN]/cervical carcinoma in situ or melanoma in situ). Prior history of other cancer is allowed as long as there is no active disease within the prior 5 years
- Major surgery within 28 days before randomization
- Positive hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection at screening
- History of non compliance to medical regimens
- Subjects unwilling to or unable to comply with the protocol
- Subject is currently receiving treatment with any agent listed on the prohibited medication list
- Treatment with any investigational product within < 4 half lives for each individual investigational product OR 28 days prior to randomization
- Current treatment with intravenous bisphosphonate or denosumab with elevated serum calcium corrected for albumin or ionized calcium levels outside institutional normal limits at screening

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

Female

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: GTx-024 9 mg Drug: GTx-024 GTx-024 softgel capsules will be administered once daily to a total dose of 9 mg	Drug: GTx-024 • To determine whether either or both doses result in an acceptable clinical benefit rate.
Experimental: GTx-024 18 mg Drug: GTx-024 GTx-024 softgel capsules will be administered once daily to a total dose of 18 mg	Drug: GTx-024 • To determine whether either or both doses result in an acceptable clinical benefit rate.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Clinical Benefit Rate, in Centrally Confirmed Androgen Receptor (AR)+ Subjects	To estimate the clinical benefit rate (defined as complete response, partial response, or stable disease) according to RECIST 1.1, in subjects with estrogen receptor positive/androgen receptor positive (ER+/AR+) BC who have centrally confirmed AR+ status. Per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) for target lesions assessed by CT or MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), >=30% decrease in the sum of the longest diameter of target lesions; Overall Response (OR) = CR + PR; Clinical Benefit Rate (CBR)= CR + PR + SD.	24 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Clinical Benefit Rate, in Full Analysis Set	To estimate the clinical benefit response rate in all subjects randomized who receive at least one dose of study medication (the FAS) regardless of AR status as determined by the central laboratory. o estimate the clinical benefit rate (defined as complete response, partial response, or stable disease) according to RECIST 1.1, in subjects with estrogen receptor positive/androgen receptor positive (ER+/AR+) BC who have centrally confirmed AR+ status. Per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) for target lesions assessed by CT or MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), >=30% decrease in the sum of the longest diameter of target lesions; Overall Response (OR) = CR + PR; Clinical Benefit Rate (CBR)= CR + PR + SD.	24 weeks

Objective Response (CR + PR) in AR+ Patients	To estimate the clinical benefit rate (defined as complete response, partial response, or stable disease) according to RECIST 1.1, in subjects with estrogen receptor positive/androgen receptor positive (ER+/AR+) BC who have centrally confirmed AR+ status. Per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) for target lesions assessed by CT or MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), >=30% decrease in the sum of the longest diameter of target lesions; Overall Response (OR) = CR + PR; Clinical Benefit Rate (CBR)= CR + PR + SD.	24 weeks
Best Overall Response in AR+ Patients	To estimate the best overall response of GTx-024 9 mg and 18 mg	From treatment initiation to end of treatment
Progression Free Survival in All Subjects	To estimate the progression free survival of subjects receiving Gtx-024 9 mg and 18 mg. Progression is defined using Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.0), as a 20% increase in the sum of the longest diameter of target lesions, or a measurable increase in a non-target lesion, or the appearance of new lesions. Subjects were assessed up through 24 months.	From randomization to tumor progression or death
Time to Progression in All Subjects	To estimate the time to progression in subjects receiving Gtx-024 9 mg and 18 mg in all subjects. Progression is defined using Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.0), as a 20% increase in the sum of the longest diameter	From randomization to tumor progression or death

	of target lesions, or a measurable increase in a non-target lesion, or the appearance of new lesions. Time to progression was assessed up through 24 months.	

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number Subjects Experiencing Adverse Events	To describe the safety profile of GTx-024 9 mg and 18 mg in all subjects randomized and treated. Reported adverse events were described by system organ class (SOC) as opposed to individual events	Up to 24 months

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

GTx

Collaborators

No information provided

Investigators

- Principal Investigator: Beth A Overmoyer, MD, Susan Smith Center for Womens Cancers, Dana Farber Cancer Institute

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2015-06-02

First Submitted that Met QC Criteria
2015-06-02

First Posted (Estimated)
2015-06-04

Results Reporting Dates

Results First Submitted
2020-09-21

Results First Submitted that Met QC Criteria
2020-12-08

Results First Posted
2020-12-09

Study Record Updates

Last Update Submitted that met QC Criteria
2020-12-08

Last Update Posted
2020-12-09

Last Verified
2020-12

More Information

Terms related to this study

Additional Relevant MeSH Terms

Neoplasms by Site
Neoplasms
Breast Diseases
Skin Diseases
Breast Neoplasms

Drug and device information, study documents, and helpful links

Study Documents

- Study Protocol and Statistical Analysis Plan (https://storage.googleapis.com/ctgov2_large_docs/32/NCT02463032/Prot_SAP_000.pdf) [PDF, 1.31MB, 2015 05 26]

ClinicalTrials.gov

Go to the classic website

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The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about-site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. The study sponsor or investigator submits information about their study to ClinicalTrials.gov and is responsible for the safety, science, and accuracy of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

COMPLETED

Study Comparing 2 Different Strategies For Management of Subjects With Plaque Psoriasis Who Have Responded to Etanercept (ReSPONSE)

ClinicalTrials.gov ID NCT00992394

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2016-01-08

Study Details Tab

Study Overview

Brief Summary

This study proposes to compare 2 different methods for managing a subject with psoriasis who has achieved good disease control, as defined by a clinical response with a Physician Global Assessment (PGA) inferior or equal to 1 at the screening visit, on etanercept treatment.

The first method involves stopping etanercept treatment on entry into the study, with the option to reinitiate etanercept at 50 mg once weekly after medical review and agreement between the subject and the investigator. The second method involves continuing on etanercept at 25 mg once weekly, with the option to increase the dose to 50 mg once weekly after medical review and agreement between the subject and the investigator. Subjects will be randomized into one of these two study arms.

Official Title

Randomized Open-label Study Comparing 2 Different Strategies For Management Of Subjects With Plaque Psoriasis Who Have Responded To Etanercept Treatment

Conditions

Psoriasis

Intervention / Treatment

- Drug: etanercept
- Drug: etanercept

Other Study ID Numbers

- 0881X1-4535
- B1801021 (Other Identifier) (OTHER: Alias Study Number)
- 2008-004439-39 (EudraCT Number)

Study Start

2010-01

Primary Completion (Actual)

2013-04

Study Completion (Actual)

2013-04

Enrollment (Actual)

174

Study Type

Feedback

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

France

Besancon, France, 25030
Centre Hopitalier St Jacques (Place St Jacques)

Limoges, France, 87042
CHU Dupuytren

Lyon Cedex 03, France, 69437
Service de Chirurgie Infantile

Nantes Cedex 01, France, 44093
C.H.U Nantes

Nice Cedex 03, France, 06202
CHU de l Archet



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Eighteen (18) years of age or older at the time of consent.
- Previously treated with etanercept for chronic plaque psoriasis for at least 12 weeks prior to the screening visit and received a total weekly dose of 50 mg per week for at least the 6 weeks preceding the day of the screening visit
- Having shown clinical response with a PGA inferior or equal to 1 at the screening visit.
- PGA inferior or equal to 1 at the baseline visit.

Exclusion Criteria:

- Evidence of skin conditions (eg, eczema) other than psoriasis that would interfere with evaluations of the effect of study medication on psoriasis.
- Evidence of active or previously known medical history of inflammatory arthritis (eg, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis).
- Any biologics other than etanercept within the 20 weeks prior to the screening visit.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Other: Arm 1 Subjects randomized to arm 1 stop their etanercept treatment on entry into the study and may be retreated by etanercept 50 mg once weekly after medical review and agreement between the subject and the investigator	Drug: etanercept • etanercept 50 mg once weekly as requested.
Other: Arm 2 Subjects randomized to arm 2 in which subjects continue on treatment with etanercept at 25 mg once weekly, but with the option to have their drug treatment increased to 50 mg once weekly after medical review and agreement between the subject and the investigator	Drug: etanercept • etanercept 25 mg or 50 mg as requested.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Time-Normalized Area Under Curve (AUC) of Physician Global Assessment (PGA) of Psoriasis Score at Week 52	PGA psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration and scaling across all psoriatic lesions. PGA of Psoriasis scale ranges from 0 (no psoriasis) to 5 (severe disease). 'Clear' and "Almost clear' includes all participants who were scored as a 0 or 1. For participants who discontinued the study before week 52, the final PGA score was carried forward to the remaining time points before calculating the 52-week AUC. The AUC was calculated on the PGA score profile with the method of trapeziums from baseline visit to visit 52. The time-normalized AUC is defined as the ratio between AUC and the expected treatment period (days): AUC/ 52 weeks*7days + 1.	Week 52

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Time-Normalized Area Under Curve (AUC) of Dermatology Life Quality Index (DLQI) at Week 52	DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire has a score range of 0 to 30 with higher scores indicating poor quality of life. An estimate of the minimal clinically important difference of the DLQI total score is a 5 point improvement. Total score range: 0 (best) to 30 (worst).	Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): The Overall Appearance of Skin, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Flaking Skin, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Redness of the	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with	Baseline to Week 52

Skin, at Baseline, Before Retreatment, and at the End of Retreatment	their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Tightness of the Skin, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Bleeding of the Skin, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Burning Sensation in the Skin, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Skin Pain, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Joint Pain, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Your Comfort Level With Your Personal Appearance, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Anxiety, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Depression, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): Fatigue, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): How Others Respond to Your Personal Appearance at Work/School, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): How Your Skin Affects Your Social and Leisure Activities, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Patient Psoriasis Satisfaction Questionnaire (PSSQ): How Satisfied	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with	Baseline to Week 52

Were You With Your Psoriasis Treatment in General? at Baseline, Before Retreatment, and at the End of Retreatment	their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	
Patient Psoriasis Satisfaction Questionnaire (PSSQ): I Would Like to Continue With my Current Psoriasis Treatment, at Baseline, Before Retreatment, and at the End of Retreatment	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Baseline to Week 52
Physician Global Assessment (PGA) of Disease Activity at Week 52	Participants completed a satisfaction survey at baseline and throughout the study. Participants were asked to rate, based on their experience during the past week, how satisfied or dissatisfied they were with their psoriasis therapy in general. Responses were based on a 5-point scale: Very dissatisfied (0) to very satisfied (4), and never had this problem (5).	Week 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2009-10-08

First Submitted that Met QC Criteria
2009-10-08

First Posted (Estimated)
2009-10-09

Results Reporting Dates

Results First Submitted
2014-04-03

Results First Submitted that Met QC Criteria
2015-12-04

Results First Posted (Estimated)
2016-01-08

Study Record Updates

Last Update Submitted that met QC Criteria
2015-12-04

Last Update Posted (Estimated)
2016-01-08

Last Verified
2015-12

More Information

Terms related to this study

Keywords Provided by Pfizer

Plaque psoriasis - etanercept - response maintenance

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti-Inflammatory Agents, Non-Steroidal
Analgesics, Non-Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti-Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Pfizer

To obtain contact information for a study center near you, click here (https://trialinfoemail.pfizer.com/pages/landing.aspx?StudyID=0881X1-4535&StudyName=Study%20Comparing%202%20Different%20Strategies%20For%20Management%20of%20Subjects%20With%20Plaque%20Psoriasis%20Who%20Have%20Responded%20to%20Etanercept)

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

The trial was terminated for several reasons, including complexities in development of LY2525623, but not because of safety concerns

A Study for Adults With Plaque Psoriasis

ClinicalTrials.gov ID NCT01018810

Sponsor Eli Lilly and Company

Information provided by Eli Lilly and Company

Last Update Posted 2011 07 29

Study Details Tab

Study Overview

Brief Summary

Feedback

In this study, we will evaluate clinical activity, safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of 5 LY2525623 dosing groups compared to placebo in adults with plaque psoriasis.

Official Title

LY2525623 (IL 23 Antibody) Multiple Dose Study in Adults With Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: LY2525623 Intravenous
- Drug: LY2525623 Subcutaneous
- Drug: Placebo Intravenous
- Drug: Placebo Subcutaneous

Other Study ID Numbers

- 11431
- I1X MC BDAD (Other Identifier) (OTHER: Eli Lilly and Company)

Study Start

2009 12

Primary Completion (Actual)

2010 05

Study Completion (Actual)

2010 08

Enrollment (Actual)

8

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Mobile, Alabama, United States, 36608
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

Arizona Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion criteria:

- Are ambulatory and greater than or equal to 18 years of age. Females of child bearing potential must test negative for pregnancy at the time of enrollment based on a serum pregnancy test and agree to use a highly reliable method of birth control as defined by those which result in a low failure rate(<1% per year) during the study.
- Chronic psoriasis vulgaris for at least 6 months prior to randomization.
- Moderate and severe (plaque) psoriasis involving at least 10% body surface area (BSA) or at least 8% BSA in subjects with severe palmar plantar involvement at randomization.
- Psoriasis Area and Severity Index (PASI) total score of at least 12 at screening.

Exclusion criteria:

- Have had a clinically significant flare of psoriasis during the 12 weeks prior to randomization or a biologic agent/monoclonal antibody within the longer of 5 half lives or 12 weeks prior to dosing, had systemic treatment for psoriasis or phototherapy within 4 weeks prior to dosing, or had topical psoriasis treatment within 2 weeks prior to dosing.
- Have had a vaccination within 4 to 12 weeks (depending on type) prior to or intend to have one within 4 weeks after the dosing period.
- Are immunocompromised or have evidence of active infection (such as viral hepatitis and/or positive testing for tuberculosis or human immunodeficiency virus [HIV]); or have had a recent serious systemic infection (such as mononucleosis or herpes zoster).
- Have a history of or current lymphoproliferative disease or malignant disease (except for resolved cervical dysplasia; or no more than 3 successfully treated basal or squamous cell carcinomas of the skin), or severe drug allergies/hypersensitivity.
- Have a history of serious cardiac disease within 12 weeks before randomization; or have serious or unstable/uncontrolled illnesses including hepatic, renal, gastroenterologic, respiratory, cardiovascular, endocrinologic, neurologic, psychiatric, immunologic, or hematologic disease and other conditions that, in the investigator s opinion, could interfere with the analyses of safety and efficacy in this study.
- Have laboratory test values outside the reference range for the population or investigative site that are considered clinically significant and/or have any of the following specific abnormalities:
    - Aspartate transaminase (AST) or alanine transaminase (ALT) >2 x the upper limit of normal (ULN; upper reference range of the central laboratory for the study)
    - Hemoglobin <100 g/L (10 g/dL)
    - White blood cell (WBC) <3.0 G/L (3,000/mm3)
    - Neutrophils <1.5 G/L (1,500/mm3)
    - Platelets <75 G/L (75,000/mm3)
    - Serum creatinine >133 µmol/L (1.5 mg/dL)
    - Random glucose >11.1mmol/L (200 mg/dL).

- Have significant allergies to humanized monoclonal antibodies, or clinically significant multiple or severe drug allergies, or intolerance to topical corticosteroids

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 180 mg LY2525623	Drug: LY2525623 Intravenous • administered intravenously at randomization and every 2 weeks for 6 weeks • Other Names: ◦ LY2525623 (IL-23 Antibody)
Placebo Comparator: Intravenous Placebo	Drug: Placebo Intravenous • administered intravenously at randomization and every 2 weeks for 6 weeks
Placebo Comparator: Subcutaneous Placebo	Drug: Placebo Subcutaneous • administered subcutaneously at randomization and every 2 weeks for 6 weeks
Experimental: 3 mg LY2525623	Drug: LY2525623 Subcutaneous • administered subcutaneously at randomization and every 2 weeks for 6 weeks • Other Names: ◦ LY2525623 (IL-23 Antibody)
Experimental: 10 mg LY2525623	Drug: LY2525623 Subcutaneous • administered subcutaneously at randomization and every 2 weeks for 6 weeks

	• Other Names: ◦ LY2525623 (IL-23 Antibody)
Experimental: 30 mg LY2525623	Drug: LY2525623 Subcutaneous • administered subcutaneously at randomization and every 2 weeks for 6 weeks • Other Names: ◦ LY2525623 (IL-23 Antibody)
Experimental: 90 mg LY2525623	Drug: LY2525623 Subcutaneous • administered subcutaneously at randomization and every 2 weeks for 6 weeks • Other Names: ◦ LY2525623 (IL-23 Antibody)

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving 75% Improvement in the Psoriasis Area and Severity Index (PASI) Scale by Week 12	PASI combines extent of body-surface involvement assessments in 4 anatomical regions and severity of regional desquamation, erythema, and plaque induration/infiltration. Overall score: 0 (no psoriasis) to 72 (severe disease). Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline through 12 weeks

Percent Improvement From Baseline in Psoriasis Area and Severity Index (PASI) Scale at Weeks 12 and 24	PASI combines body-surface assessments and severity of desquamation, erythema, and plaque induration/infiltration. Overall score:0(no psoriasis) to 72(severe disease). Percent(%) improvement=(baseline PASI-observed PASI)/baseline PASI*100. Study BDAD was terminated after enrolling only 8 patients. Least Squares (LS) Mean Values were adjusted for time, treatment, and baseline. Given small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks, 24 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Relative Physician s Global Assessment (rPGA) Scale at 12 Weeks and 24 Weeks	The rPGA rates the subject s psoriasis relative to baseline as 1 (100% clearing), 2 (excellent; 75%-99% clearing), 3 (good; 50%-74% clearing), 4 (fair; 25%-49% clearing), 5 (poor; 0%-24% clearing), or 6 (worsening). Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks, 24 weeks

Change From Baseline in the Visual Analog Scale (VAS) for Psoriatic Arthritis at 12 Weeks and 24 Weeks	A global estimate of pain caused by joint disease on arising made by the subject by placing a vertical mark or tick on a 100-mm VAS from not present to worse, range from 0 to 100mm. Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks, 24 weeks
Change From Baseline in the Patient s Global Assessment of Psoriasis Scale at 12 Weeks and 24 Weeks	A scale measures patient perception of psoriatic condition with a continuous range of 0 (good) to 5 (severe). Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks, 24 weeks
Change From Baseline in the Dermatology Life Quality Index (DLQI) Score at 12 Weeks	10-item, validated questionnaire covers 6 domains. Responses range from 0 (not at all) to 3 (very much); totals range from 0 to 30 (more impairment). Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks
Change From Baseline in the 16-Item Quick Inventory for	A 16-item patient-rated measure of depressive symptomatology. The total score ranges from 0 to 27 with higher scores indicative of greater severity. Study BDAD was terminated after	Baseline, 12 weeks

Depressive Symptomatology-Self Report (QIDS16SRTotal) at 12 Weeks	enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	
Change From Baseline in the Hospital Anxiety and Depression Scale (HADS) at 12 Weeks	A 14-item questionnaire with anxiety and depression subscales; 21 maximum score. Scores of 11+ on either subscale (significant case of psychological morbidity); 8-10 (borderline); 0-7 (normal). Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline, 12 weeks
Pharmacokinetics: Area Under the Time Concentration Curve Through 24 Weeks	Area under the curve of serum drug concentration, including absolute bioavailability. Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and in each treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline through 24 weeks
Number of Participants Who Developed Anti-LY2525623 Antibody Results Through 24 Weeks	Measures anti-LY2525263 antibody as positive or negative. Study BDAD was terminated after enrolling only 8 patients. Given the small sample size overall and per treatment arm, numerical summaries and statistical comparisons are not appropriate and may be scientifically/clinically misleading; therefore, this outcome measure was not analyzed.	Baseline through 24 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Eli Lilly and Company

Collaborators

No information provided

Investigators

- Study Director: Call 1 877 CTLILLY (1 877 285 4559) or 1 317 615 4559 Mon Fri 9 AM 5 PM Eastern time (UTC/GMT 5 hours, EST), Eli Lilly and Company

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted

2009-11-24

First Submitted that Met QC Criteria

2009-11-24

First Posted (Estimated)

2009-11-25

Results Reporting Dates

Results First Submitted

2011-06-01

Results First Submitted that Met QC Criteria

2011-06-01

Results First Posted (Estimated)

2011-06-30

Study Record Updates

Last Update Submitted that met QC Criteria

2011-07-27

Last Update Posted (Estimated)

2011-07-29

Last Verified

2011-07

More Information

Terms related to this study

Keywords Provided by Eli Lilly and Company

Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs

Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Growth Inhibitors
Antineoplastic Agents
Interleukin 23
Antibodies
Immunoglobulins

Study Documents

No study documents available

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study to Evaluate Remicade (Infliximab) in Moderate-to-Severe Chronic Plaque Psoriasis in the Middle Eastern Population (Study P04528)

ClinicalTrials.gov ID NCT00687362

Sponsor Merck Sharp & Dohme LLC

Information provided by Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted 2017 05 10

Study Details Tab

Study Overview

Brief Summary

Middle Eastern subjects with moderate to severe chronic plaque psoriasis will be administered infusions of infliximab (Remicade) at 5 mg/kg of body weight at Weeks 0, 2, 6, 14, and 22. The safety and efficacy of infliximab monotherapy will be evaluated.

Feedback

Official Title

A Multicenter, Multinational, Open Label Study on the Efficacy and Safety of Infliximab Monotherapy in Moderate to severe Chronic Plaque Psoriasis in Middle Eastern Population

Conditions

Psoriasis

Intervention / Treatment

- Biological: Infliximab

Other Study ID Numbers

- P04528

Study Start (Actual)

2006 05 30

Primary Completion (Actual)

2008 11 11

Study Completion (Actual)

2008 11 11

Enrollment (Actual)

22

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Infliximab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Infliximab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- 18 years or older, either gender, and any race.
- Psoriasis affecting >=5% of body surface, PASI score >=10 (maximum score 72).
- History of plaque psoriasis for >6 months.
- Informed written consent.
- Refractory to other anti psoriasis agents (topical corticosteroids, phototherapy UVa [PUVA], or systemic therapy).
- Negative chest x ray and purified protein derivative (PPD) within 1 month.
- Understand and be able to adhere to dosing and visit schedules.
- Screening laboratory tests must meet protocol specified criteria.
- Women and men of childbearing potential must be using adequate birth control measures and should continue such precautions for 6 months after last infusion of infliximab.

Exclusion Criteria:

- Pregnant, nursing, or planned pregnancy within 6 months after last scheduled treatment.
- Used topical corticosteroids in previous 14 days or systemic therapy (phototherapy UVb [UVB], PUVA, cyclosporine, methotrexate) in previous 28 days, or received treatment with anti tumor necrosis factor (TNF) alpha monoclonal antibodies, human or murine immunoglobulins, TNF alpha receptor fusion proteins, or other bioengineered fusion proteins.
- Received previous immunobiologics.
- Have HIV, hepatitis B or C.
- Recently transplanted (exception corneal transplant >3 months prior to first infusion) or known malignancy or history of malignancy within previous 5 years (exception basal or squamous cell carcinoma of skin that has been treated with no evidence of recurrence).
- Concurrent medications that are not permitted.
- congestive heart failure (CHF)
- Use of cyclosporine or tacrolimus within 4 weeks prior to Screening.
- Use of intramuscular (IM), intravenous (IV), or oral corticosteroids within 4 weeks prior to Screening.
- Treatment with any investigational drug within 3 months prior to Screening.
- Allergy to murine proteins.
- Serious infections (hepatitis, pneumonia, pyelonephritis) in previous 3 months.
- History of active tuberculosis (TB) requiring treatment within previous 3 years, or history of opportunistic infections (herpes zoster) within 2 months of Screening.
- Current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, endocrine, pulmonary, cardiac, neurological or cerebral disease.
- Current signs or symptoms of other severe uncontrolled disease which in investigator s opinion would put the subject at an unacceptable risk.
- History of current alcohol or drug abuse.

- Not observed designated washout periods for any of the prohibited medications in protocol.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Infliximab 5 mg/kg Infliximab 5 mg/kg of body weight given as an infusion at Weeks 0, 2, 6, 14, and 22.	Biological: Infliximab • Infliximab 5 mg/kg of body weight given as an infusion at Weeks 0, 2, 6, 14, and 22. • Other Names: ◦ Remicade, SCH 215596

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area and Severity Index 75 (PASI75) Response at Week 10	PASI 75 response is defined as participants who achieved at least a 75% improvement in PASI score from Baseline to Week 10. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72 (the higher the number, the worse the disease).	10 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck Sharp & Dohme LLC

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2008-05-27

First Submitted that Met QC Criteria
2008-05-27

First Posted (Estimated)
2008-05-30

Results Reporting Dates

Results First Submitted
2010-02-17

Results First Submitted that Met QC Criteria
2010-02-17

Results First Posted (Estimated)
2010-03-09

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-04

Last Update Posted
2017-05-10

Last Verified

2017-04

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Dermatologic Agents
Gastrointestinal Agents
Antirheumatic Agents
Infliximab

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

http://www.merck.com/clinical trials/pdf/Merck%20Procedure%20on%20Clinical%20Trial%20Data%20Access%20Final_Updated%20July_9_2014.pdf

http://engagezone.msd.com/ds_documentation.php

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Phase II Efficacy Study Looking at a Single-dose of One of Three Dose Levels of AIN457 in Patients With Chronic Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT00770965**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2018 03 12

Study Details Tab

Study Overview

Brief Summary

This is an exploratory, 4 arm, parallel group, placebo controlled study comparing three doses of AIN457 to placebo. Subjects with a diagnosis of moderate to severe chronic plaque psoriasis will be randomized to receive either AIN457 at one of the three doses studied or placebo.

Feedback

Official Title

Phase II Single Dose, Randomized, Double blind, Multi center, Parallel group, Placebo controlled Study to Assess the Efficacy of Three Dose Levels of AIN457 in Patients With Chronic Plaque type Psoriasis

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Biological: AIN457
- Biological: Placebo

Other Study ID Numbers

- CAIN457A2204

Study Start (Actual)

2008 09 10

Primary Completion (Actual)

2009 09 17

Study Completion (Actual)

2009 09 17

Enrollment (Actual)

80

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard)
resources: Chronic Graft Versus Host Disease
(https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Santa Monica, California, United States, 90404
Novartis Investigative Site

Kentucky Locations

Louisville, Kentucky, United States, 40217
Novartis Investigative Site

North Carolina Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Diagnosis of plaque psoriasis for at least 6 months prior to screening. The patients must meet all of the following criterion:
    1. Coverage of the body surface area (BSA) of 10% or more with plaques
    2. A score of 3 or more on the IGA (Investigator Global Assessment) scale
    3. A PASI score of at least 12 at baseline;

Exclusion Criteria:

- Have forms of psoriasis other than the required "plaque psoriasis"
- Women of childbearing potential
- Recent use of investigational drugs or treatment with other biological therapies (wash out periods required)
- Previous treatment with this investigational drug
- Subjects with active or history of clinically significant cardiac, kidney or liver abnormalities

Other protocol defined inclusion/exclusion criteria may have applied.

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 0.3 mg/kg Participants received AIN457 0.3 mg/kg IV on Day 1.	Biological: AIN457
Experimental: AIN457 1.0 mg/kg Participants received AIN457 1.0 mg/kg IV on Day 1.	Biological: AIN457
Experimental: AIN457 3.0 mg/kg Participants received AIN457 3.0 mg/kg IV on Day 1.	Biological: AIN457
Placebo Comparator: Placebo Participants received placebo to AIN457A IV on day 1.	Biological: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Psoriasis Area and Severity Index (PASI) Scores	This study was not powered for efficacy. Due to audit findings at one site, which included 65 participants, all participants enrolled at the site were excluded from the planned efficacy analyses. As a result, efficacy could not be analyzed due to an insufficient number of participants.	baseline, week 4

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in PASI	This study was not powered for efficacy. Due to audit findings at one s te, which included 65 participants, all participants enrolled at site were excluded from the planned efficacy analyses. As a result, efficacy could not be analyzed due to an insufficient number of participants.	baseline, weeks 12, 14, 16, 20, 24, 28 and 32
Investigator Global Assessment (IGA) Scores	This study was not powered for efficacy. Due to audit findings at one s te, which included 65 participants, all participants enrolled at the site were excluded from the planned efficacy analyses. As a result, efficacy could not be analyzed due to an insufficient number of participants.	baseline, day 1, weeks 1, 2, 4, 6, 8, 10, 12, 14, 16, 20, 24, 28, 32

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals
- Principal Investigator: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted

2008-10-09

First Submitted that Met QC Criteria

2008-10-09

First Posted (Estimated)
2008-10-10

Results Reporting Dates

Results First Submitted
2015-02-02

Results First Submitted that Met QC Criteria
2015-02-02

Results First Posted (Estimated)
2015-02-18

Study Record Updates

Last Update Submitted that met QC Criteria
2018-02-12

Last Update Posted
2018-03-12

Last Verified
2018-02

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Plaque psoriasis, skin condition, thickening, flaking, skin disease, autoimmune disease

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Effectiveness of Adalimumab (HUMIRA®) in the Treatment of Scalp and Nail Affection in Patients With Moderate to Severe Plaque Psoriasis in Routine Clinical Practice

ClinicalTrials.gov ID NCT01202565

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2014 08 07

Study Details Tab

Study Overview

Brief Summary

Feedback

There is clearly a need for further data on the efficacy of biologic agents in the treatment of nail and scalp psoriasis, especially in the routine clinical setting. A few case reports can be found, but no published data exists from non interventional studies, such as post marketing observational studies (PMOS) that reflect routine clinical practice.

The aim of this PMOS is to evaluate the long term (12 month) efficacy of adalimumab in the treatment of nail and scalp psoriatic lesions in routine dermatologic practice.

Detailed Description

This is post marketing observational study (PMOS) in which HUMIRA® is prescribed in the usual manner in accordance with the terms of the local marketing authorization with regards to dose, population and indication, and following the local prescription and/or reimbursement guidance.

Follow up visits are not strictly scheduled, but rather left to the judgment of each investigator within the 12 month study period for each participant. Five visits are indicated within the 12 month observational period: Baseline and follow up at 3 months, 6 months, 9 months and at 12 months (Study End).

As nails are not included in the general measures of disease severity (such as Psoriasis Area and Severity Index [PASI]), the Nail Psoriasis Severity Index (NAPSI) will be used to assign a score of nail psoriasis. The scalp, though being involved in the general measures of disease severity (e.g. PASI), represents only 4 5% of the body surface and is therefore poorly represented. Psoriasis Scalp Severity Index (PSSI) will be used to quantify the intensity of scalp psoriasis and its changes during the study. The association between general skin and localized nail and scalp, and changes in quality of life in response to adalimumab therapy will also be examined.

Official Title

Effectiveness of Adalimumab (Humira) in the Treatment of Scalp and Nail Affection in Patients With Moderate to Severe Plaque Psoriasis in Routine Clinical Practice

Conditions

Moderate to Severe Plaque Psoriasis

Intervention / Treatment

Other Study ID Numbers

- P12 165

Study Start

2010 09

Primary Completion (Actual)

2013 07

Study Completion (Actual)

2013 07

Enrollment (Actual)

506

Study Type

Observational

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Czech Republic

Chotoviny, Czech Republic, 391 32
Site Reference ID/Investigator# 63776

Jihlava, Czech Republic, 58601
Site Reference ID/Investigator# 58083

Klimkovice, Czech Republic, 74283
Site Reference ID/Investigator# 56762

Klimkovice, Czech Republic, 74283

Click to view interactive map

Site Reference ID/Investigator# 56763

Kostelec nad Ohri, Czech Republic, 517

41

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

Patients will be enrolled in this PMOS if they fulfill all of the below criteria:

1. Patients with moderate to severe plaque psoriasis eligible for Humira therapy according to the local product label and prescription/reimbursement guidelines
2. Have significant psoriatic nail affection (total Nail Psoriasis Severity Index NAPSI score of hands and feet ≥ 10) and/or significant psoriatic scalp affection (Psoriasis Scalp Severity Index PSSI score ≥ 10)
3. Adult (≥18 years of age)
4. Have negative result of tuberculosis (TB) screening test or TB prophylaxis as per local guidelines
5. Willing to provide informed consent if requested by the local law regulations

Exclusion Criteria:

Patients fulfilling any of the below exclusion criteria will not be eligible for this PMOS:

1. Meet contraindications as outlined in the latest version of the local Summary of Product Characteristics (SmPC)
2. Participate in another clinical/observational study

Study Population

Per this PMOS protocol, the study population will consists of adult patients with moderate to severe plaque psoriasis who have failed to respond to, have a contraindication to, or are intolerant of other systemic therapies including cyclosporine, methotrexate or PUVA (photochemotherapy combining psoralen with ultraviolet A treatment), and exhibit a significant psoriatic affection of the scalp and/or nails.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Non Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Time Perspective: Prospective

Cohorts and Interventions

Group/Cohort
Adalimumab Participants with moderate to severe plaque psoriasis received adalimumab (Humira®) therapy according to the local product label and prescription/reimbursement guidelines.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in Nail Psoriasis Severity Index (NAPSI) to Month 12	NAPSI grades nails for both nail matrix psoriasis and nail bed psoriasis. The sum of these two scores is the total score for that nail. Nail matrix psoriasis consists of any of the following: pitting, leukonychia, red spots in the lunula, or nail plate crumbling. Nail bed psoriasis is the presence or absence of onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration or nail bed hyperkeratosis. Scoring for each is based on the following scale:	Baseline and Month 12

	• 0 = none; • 1 = present in 1/4 nail quadrants; • 2 = present in 2/4 nail quadrants; • 3 = present in 3/4 nail quadrants; • 4 = present in 4/4 nail quadrants. The 2 most affected nails on either hands or feet were evaluated and summed for a score ranging from 0 (no nail psoriasis) to 16 (psoriasis in 4/4 nail quadrants). Change from Baseline is presented as a percentage of the Baseline value, calculated as: Month 12 value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	
Percent Change From Baseline in Psoriasis Scalp Severity Index (PSSI) to Month 12	The PSSI consists of two parts: an assessment of scalp area involved and an assessment of the 3 clinical symptoms erythema, induration and desquamation. Involved scalp area is measured on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved), clinical symptoms are each rated from 0 (absent) to 4 (severest possible). The composite score ranges from 0 (best) to 72 (worst) and is derived from the sum of symptom scores multiplied by the score of involved scalp area. Change from Baseline is presented as a percentage of the Baseline value: Month 12 value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Month 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Change From Baseline in Nail Psoriasis Severity Index (NAPSI)	NAPSI grades nails for both nail matrix psoriasis and nail bed psoriasis. The sum of these two scores is the total score for that nail. Nail matrix psoriasis consists of any of the following: pitting, leukonychia, red spots in the lunula, or nail plate crumbling. Nail bed psoriasis is the presence or absence of onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration or nail bed hyperkeratosis. Scoring for each is based on the following scale: • 0 = none; • 1 = present in 1/4 nail quadrants; • 2 = present in 2/4 nail quadrants; • 3 = present in 3/4 nail quadrants; • 4 = present in 4/4 nail quadrants. The 2 most affected nails on either hands or feet were evaluated and summed for a score ranging from 0 (no nail psoriasis) to 16 (psoriasis in 4/4 nail quadrants). A negative change from Baseline indicates improvement.	Baseline and Months 3, 6, 9, and 12
Percentage of Participants Achieving a Good Clinical Response on Nail Psoriasis	Good clinical response on nails is defined as ≥ 50% improvement from Baseline in total NAPSI score. The NAPSI grades nails for both nail matrix psoriasis and nail bed psoriasis. The sum of these two scores is the total score for that nail. Nail matrix psoriasis consists of any of the following: pitting, leukonychia, red spots in the lunula, or nail plate crumbling. Nail bed psoriasis is the presence or absence of onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration or nail bed hyperkeratosis. Scoring for each is based on the following scale:	Baseline and Months 3, 6, 9, and 12

	• 0 = none; • 1 = present in 1/4 nail quadrants; • 2 = present in 2/4 nail quadrants; • 3 = present in 3/4 nail quadrants; • 4 = present in 4/4 nail quadrants. The 2 most affected nails on either hands or feet were evaluated and summed for a score ranging from 0 (no nail psoriasis) to 16 (psoriasis in 4/4 nail quadrants).	
Percentage of Participants Achieving Complete Clearing of Nails	Complete clearing of nails is defined as a total NAPSI score of zero. The NAPSI grades nails for both nail matrix psoriasis and nail bed psoriasis. The sum of these two scores is the total score for that nail. Nail matrix psoriasis consists of any of the following: pitting, leukonychia, red spots in the lunula, or nail plate crumbling. Nail bed psoriasis is the presence or absence of onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration or nail bed hyperkeratosis. Scoring for each is based on the following scale: • 0 = none; • 1 = present in 1/4 nail quadrants; • 2 = present in 2/4 nail quadrants; • 3 = present in 3/4 nail quadrants; • 4 = present in 4/4 nail quadrants. The 2 most affected nails on either hands or feet were evaluated and summed for a score ranging from 0 (no nail psoriasis) to 16 (psoriasis in 4/4 nail quadrants).	Months 3, 6, 9, and 12
Change From Baseline in Psoriasis Scalp	The PSSI consists of two parts: an assessment of scalp area involved and an assessment of the 3 clinical symptoms erythema, induration and desquamation. Involved scalp area is measured	Baseline and Months

Severity Index (PSSI)	on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved), clinical symptoms are each rated from 0 (absent) to 4 (severest possible). The composite score ranges from 0 (best) to 72 (worst) and is derived from the sum of symptom scores multiplied by the score of involved scalp area. A negative change from Baseline indicates improvement.	3, 6, 9, and 12
Percentage of Participants Achieving Good Clinical Response on Scalp	Good clinical response on scalp is defined as a ≥ 50% improvement from Baseline in PSSI score. The PSSI consists of two parts: an assessment of scalp area involved and an assessment of the 3 clinical symptoms erythema, induration and desquamation. Involved scalp area is measured on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved), clinical symptoms are each rated from 0 (absent) to 4 (severest possible). The composite score ranges from 0 (best) to 72 (worst) and is derived from the sum of symptom scores multiplied by the score of involved scalp area.	Baseline and Months 3, 6, 9, and 12
Percentage of Participants Achieving Complete Clearing of Scalp	Complete clearing on scalp is defined as a PSSI score of zero. The PSSI consists of two parts: an assessment of scalp area involved and an assessment of the 3 clinical symptoms erythema, induration and desquamation. Involved scalp area is measured on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved), clinical symptoms are each rated from 0 (absent) to 4 (severest possible). The composite score ranges from 0 (best) to 72 (worst) and is derived from the sum of symptom scores multiplied by the score of involved scalp area.	Months 3, 6, 9, and 12

Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score	The Psoriasis Area and Severity Index (PASI) score is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease. Change from Baseline is presented as a percentage of the Baseline value: Month 12 value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Month 12
Change From Baseline in PASI Score	The Psoriasis Area and Severity Index (PASI) score is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease. A negative change from Baseline indicates improvement.	Baseline and Months 3, 6, 9, and 12
Percentage of Participants Achieving a PASI 90 Response	The percentage of participants with a ≥ 90% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1),	Baseline and Months 3, 6, 9, and 12

	moderate (2), severe (3) or very severe (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	
Percentage of Participants Achieving a PASI 75 Response	The percentage of participants with a ≥ 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline and Months 3, 6, 9, and 12
Percentage of Participants Achieving a PASI 50 Response	The percentage of participants with a ≥ 50% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score	Baseline and Months 3, 6, 9, and 12

	ranges from 0 to 72. The higher the total score, the more severe the disease.	
Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Score	The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment related feelings. Participants answer 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is 0 to 30. A score of 21 to 30 means an extremely large effect on the participant s life whereas 0-1 means that the disease has no effect at all. Change from Baseline is presented as a percentage of the Baseline value: Month 12 value - Baseline value / Baseline value * 100. A negative change from Baseline indicates improvement.	Baseline and Month 12
Change From Baseline in DLQI Score	The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment related feelings. Participants answer 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is 0 to 30. A score of 21 to 30 means an extremely large effect on the participant s life whereas 0-1 means that the disease has no effect at all. A negative change from Baseline indicates improvement.	Baseline and Months 3, 6, 9, and 12
Associations Between General Improvement in Psoriasis With	Associations between general improvement in psoriasis, measured by percentage change of PASI, and the improvement of nail psoriasis at the same time, measured by percentage improvement of the NAPSI, were evaluated by	Baseline and Month 12

Improvement in Nail Psoriasis	means of Spearmans rank correlation coefficient. Generally, correlation coefficients below 0.2 are considered as no or only weak association, between 0.2 and 0.5 as moderate association, between 0.5 and 0.8 as strong association and above 0.8 as very strong associations.	
Associations Between General Improvement in Psoriasis With Improvement in Scalp Psoriasis	Associations between general improvement in psoriasis, measured by percentage change of PASI, and the improvement of scalp psoriasis at the same time, measured by percentage improvement of the PSSI, were evaluated by means of Spearmans rank correlation coefficient. Generally, correlation coefficients below 0.2 are considered as no or only weak association, between 0.2 and 0.5 as moderate association, between 0.5 and 0.8 as strong association and above 0.8 as very strong associations.	Baseline and Month 12
Associations Between Improvement in Quality of Life With Improvement in Nail Psoriasis	Associations between general improvement in quality of life, measured by percentage change of DLQI, and the improvement of nail psoriasis at the same time, measured by percentage improvement of the NAPSI, were evaluated by means of Spearmans rank correlation coefficient. Generally, correlation coefficients below 0.2 are considered as no or only weak association, between 0.2 and 0.5 as moderate association, between 0.5 and 0.8 as strong association and above 0.8 as very strong associations.	Baseline and Month 12
Associations Between Improvement in Quality of Life With	Associations between general improvement in quality of life, measured by percentage change of DLQI, and the improvement of scalp psoriasis at the same time, measured by percentage improvement of the PSSI, were evaluated by means of Spearmans rank correlation	Baseline and Month 12

Improvement in Scalp Psoriasis	coefficient. Generally, correlation coefficients below 0.2 are considered as no or only weak association, between 0.2 and 0.5 as moderate association, between 0.5 and 0.8 as strong association and above 0.8 as very strong associations.	
Associations Between General Improvement in Psoriasis With Improvement in Quality of Life	Associations between general improvement in quality of life, measured by percentage change of DLQI, and general improvement in psoriasis at the same time, measured by percentage improvement of the PASI, were evaluated by means of Spearmans rank correlation coefficient. Generally, correlation coefficients below 0.2 are considered as no or only weak association, between 0.2 and 0.5 as moderate association, between 0.5 and 0.8 as strong association and above 0.8 as very strong associations.	Baseline and Month 12

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

No information provided

Investigators

- Study Director: Jaka Brumen, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-09-14

First Submitted that Met QC Criteria
2010-09-14

First Posted (Estimated)
2010-09-16

Results Reporting Dates

Results First Submitted
2014-07-15

Results First Submitted that Met QC Criteria
2014-07-15

Results First Posted (Estimated)
2014-08-07

Study Record Updates

Last Update Submitted that met QC Criteria
2014-07-15

Last Update Posted (Estimated)
2014-08-07

Last Verified

2014-07

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Post marketing observational study (PMOS) Protocol
Moderate to Severe Plaque Psoriasis
Treatment of Scalp and Nail Affection
Effectiveness of Adalimumab (HUMIRA®)

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related Info (http://rxabbvie.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Multiple-dose Regimen Study to Assess Effect of 12 Months of Secukinumab Treatment on Skin Response and Biomarkers in Psoriasis Patients

ClinicalTrials.gov ID **NCT01537432**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2016 01 05

Study Details Tab

Study Overview

Brief Summary

Feedback

This study is designed to evaluate the proportion of patients achieving reversal of chronic plaque psoriasis at week 4 and 12 following multiple doses of secukinumab administered subcutaneously (sc) compared to placebo. Starting from week 13, all patients will receive multiple doses of secukinumab up to week 52 to study long term effects of secukinumab. Clinical endpoints including biomarker assessments, PASI, IGA and DLQI will be compared to better understand, why secukinumab may be effective in psoriasis patients.

Official Title

Phase II Randomized Double Blinded Placebo Controlled, Multiple dose Regimen Study to Assess the Rate of Histological Clearance and Effect on Molecular Pathways as Well as on Biomarkers of 12 Months Secukinumab 300 mg s.c. Treated Patients With Chronic Plaque type Psoriasis

Conditions

Psoriasis, Plaque type Psoriasis

Intervention / Treatment

- Drug: secukinumab
- Drug: placebo

Other Study ID Numbers

- CAIN457A2223

Study Start

2012 01

Primary Completion (Actual)

2014 12

Study Completion (Actual)

2014 12

Enrollment (Actual)

36

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 35205
Novartis Investigative Site

California Locations

Pasadena, California, United States, 91105
Novartis Investigative Site

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion criteria:

- Chronic plaque type psoriasis diagnosed for at least 6 months
- Moderate to severe psoriasis as defined by: PASI score of ≥12, IGA score of ≥3, BSA (body surface area) affected by plaque type psoriasis of ≥10%
- Chronic plaque type psoriasis considered inadequately controlled by: topical treatment and/or; phototherapy and/or previous systemic therapy

Exclusion criteria:

- Forms of psoriasis other than chronic plaque type
- Evidence of skin conditions at the time of the screening visit (e.g., eczema) that would interfere with evaluations of the effect of the investigational product on psoriasis
- History or evidence of active tuberculosis or evidence of latent tuberculosis (or other infections like Hepatitis C/B), malignancy; active or known use of other immunosuppressive drugs (for eg: AIDs, RA, organ rejection etc.) at the screening visit
- Pregnant or nursing (lactating) women

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: placebo placebo	Drug: placebo • placebo comparator
Experimental: secukinumab secukinumab	Drug: secukinumab • secukinumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving Skin Histology Response After Secukinumab Treatment From Baseline to Week 12	Histological sections of lesional and nonlesional skin biopsies at baseline and at Week 12 were examined. For each visit, each patient s lesional skin biopsy was scored for the degree of histological improvement compared to that patient s baseline disease on a five point scale; - 1 (worse) to +3 (excellent). Histological disease reversal or "excellent improvement" (histological disease reversal score = 3) was declared at the	Baseline, Week 12

	endpoint when all of the following four criteria were met.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving Skin Histological Disease Reversal at Week 52	Histological sections of lesional and nonlesional skin biopsies at Week 52 were examined. For each visit, each patient s lesional skin biopsy was scored for the degree of histological improvement compared to that patient s baseline disease on a five point scale; - 1 (worse) to +3 (excellent). Histological disease reversal or "excellent improvement" (histological disease reversal score = 3) was declared at the endpoint when all of the following four criteria were met.	Week 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-02-17

First Submitted that Met QC Criteria
2012-02-17

First Posted (Estimated)
2012-02-23

Results Reporting Dates

Results First Submitted
2015-12-01

Results First Submitted that Met QC Criteria
2015-12-01

Results First Posted (Estimated)
2016-01-05

Study Record Updates

Last Update Submitted that met QC Criteria

2015-12-01

Last Update Posted (Estimated)

2016-01-05

Last Verified

2015-11

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis, Plaque type psoriasis
Plaque
Secukinumab
AIN457A
PASI
DLQI
IGA

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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COMPLETED

Immediate Response With Adalimumab and Its Impact on Quality of Life and Other Comorbidity Factors in Patients With Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT01265823**

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2013 03 11

Study Details Tab

Study Overview

Brief Summary

Feedback

W11 050 is a Mexican open label multicenter study that has been designed to further assess the safety and efficacy of adalimumab in the treatment of patients with active plaque psoriasis who have failed prior conventional systemic psoriasis treatment or who are candidates for systemic therapy.

Detailed Description

Up to 150 subjects having a diagnosis of active plaque psoriasis and fulfilling the study eligibility criteria were enrolled in Mexico. Adalimumab was administered as follows: 80 mg at baseline, followed by 40 mg every other week (eow; starting at week 1 until week 15). The study drug was self administered via subcutaneous (sc) injection. Safety and efficacy measures were performed throughout the study.

Official Title

Immediate Response With Adalimumab and Its Impact on Quality of Life and Other Comorbidity Factors in Patients With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Biological: Adalimumab

Other Study ID Numbers

- W11 050

Study Start

2010 10

Primary Completion (Actual)

2012 02

Study Completion (Actual)

2012 02

Enrollment (Actual)

150

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Mexico

Circuito Comercial Satelite, Mexico
Site Reference ID/Investigator# 50942

Iztapalapa, Mexico, 04230
Site Reference ID/Investigator# 40964

Mexico City, Mexico, 06780
Site Reference ID/Investigator# 50943

Monterrey, Mexico, 64460
Site Reference ID/Investigator# 40965

Monterrey, Mexico, 64718
Site Reference ID/Investigator# 40962



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Able and willing to give written informed consent prior to any study related procedures and to comply with the requirements of the study protocol
2. Male and female subjects between 18 and 75 years old
3. Diagnosis of moderate to severe types I and II plaque psoriasis (Type I : symptoms onset before 40 years old; Type II: symptoms onset after 40 years old), with at least 6 months of duration
4. Documented moderate to severe plaque psoriasis based on Psoriasis Area and Severity Index (PASI) score >10
5. Subjects naïve to adalimumab therapy
6. Subject must be evaluated for active and latent tuberculosis (TB) infection by using a Purified Protein Derivative (PPD) skin test, chest x ray (posterior to anterior (PA) and lateral views) and a detailed review of the subject s medica history. This screening must be negative
7. A negative pregnancy test (serum human chorionic gonadotrophin) for women of childbearing potential prior to start of study treatment. (Non childbearing potential is defined as postmenopausal for at least 1 year or surgically sterile [bilateral tubal ligation, bilateral oophorectomy or hysterectomy])
8. Able and willing to self administer subcutaneous injections or have available a suitable person to administer subcutaneous injections
9. Subject is judged to be in generally good health as determined by the investigator

Exclusion Criteria:

1. Prior treatment with any investigational agent within 30 days, or five half lives of the product, which ever is longer. Subject has been treated with any investigational drug of chemical or biologic nature within a minimum of 30 days or five half lives (whichever is longer) of the drug prior to study entry (Baseline Visit)
2. Subject has other active skin diseases or skin infections (bacterial, fungal, or viral) that may interfere with the evaluation of psoriasis or compromise the subject s safety
3. Subject has a history of dysplasia, malignancy (including lymphoma and leukemia), or lymphoproliferative disease other than: a. Successfully and completely treated non metastatic squamous or basal cell carcinoma of the skin with no recurrence within the last five years. b. Localized carcinoma in situ of the cervix or cervical dysplasia, with no recurrence within the last five years
4. Persistent or recurrent infections or severe infections requiring hospitalization or treatment with intravenous (IV) antibiotics, IV antivirals, or IV antifungals within 30 days, or oral antibiotics, oral antivirals or oral antifungals within 14 days prior to Baseline Visit
5. Other medical conditions: uncontrolled diabetes, unstable ischemic heart disease, congestive heart failure New York Heart Association (NYHA) III IV, recent stroke (within three months), chronic leg ulcer and any other condition (e.g., indwelling urinary catheter) which, in the opinion of the investigator, may place the subject at risk

6. Previous diagnosis or signs highly indicative of central nervous system demyelinating diseases (e.g., optic neuritis, ataxia, apraxia)
7. History of listeriosis, histoplasmosis, chronic or active Hepatitis B infection, human immunodeficiency virus (HIV) infection, immunodeficiency syndrome, chronic recurring infections or active TB
8. Female subjects who are pregnant or breast feeding
9. History of clinically significant drug or alcohol abuse in the last year
10. Subject started receiving a new topical therapy within the last four weeks prior to the Baseline visit for areas other than the palms, soles of feet, axilla and groin
11. Subject started being treated with ultraviolet B (UVB) phototherapy, within the last four weeks prior to the Baseline visit
12. Subject was treated with psoralen ultraviolet A (PUVA) phototherapy within the last four weeks prior to the Baseline visit
13. Subject has been initiated on a new systemic agent within the last four weeks prior to the Baseline visit
14. Patients with history of atopy
15. Patients with any other autoimmune disease such as systemic lupus erythematosus (SLE) , Sdx Sjögren, vasculitis etc
16. Known hypersensitivity to the excipients of adalimumab as stated in the label
17. Female subjects who are pregnant or breast feeding or considering becoming pregnant during the study
18. Subject is considered by the investigator, for any reason, to be an unsuitable candidate for the study
19. Subject with any prior exposure to Tysabri (natalizumab), or Orencia (abatacept)
20. Subjects with positive immunologic test for hepatitis A, B or C (Positive test of any of the following: hepatitis A viral antibody immunoglobulin M (HAV IgM), hepatitis B surface antigen (HBsAg) or hepatitis C virus antibody (HCV Ab)
21. Subjects with a positive immunologic test for HIV determined by enzyme linked immunosorbent assay (ELISA) method

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non Randomized
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Adalimumab	Biological: Adalimumab • Adalimumab was administered as follows: 80 mg at baseline, followed by 40 mg every other week (eow; starting at Week 1 until Week 15). The study drug was self-administered via subcutaneous (sc) injection. • Other Names: ◦ ABT-D2E7 ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Psoriasis	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening),	Week 4

Area and Severity Index (PASI)-75 Response at Week 4	induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI-75 response is the percentage of participants who achieved at least a 75% reduction (improvement) from baseline in PASI score at Week 4. The improvement in PASI score was used as a measure of efficacy.	
Percentage of Participants With Psoriasis Area and Severity Index (PASI)-75 Response at Week 16	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI-75 response is the percentage of participants who achieved at least a 75% reduction (improvement) from baseline in PASI score at Week 16. The improvement in PASI score was used as a measure of efficacy.	Week 16
Percentage of Participants With a Dermatology Life Quality Index (DLQI) Score < 6 at Week 4	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much (score of 3), a lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired. A score <6 indicates that psoriasis has small or no effect at all on participant s life.	Week 4
Percentage of Participants With a Dermatology Life Quality	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week.	Week 16

Index (DLQI) Score < 6 at Week 16	Responses to each are: very much (score of 3), a lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired. A score <6 indicates that psoriasis has small or no effect at all on participant s life.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Score of Dermatology Life Quality Index (DLQI) at Baseline and Week 4	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much (score of 3), a lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired.	Baseline, Week 4
Mean Score of Dermatology Life Quality Index (DLQI) at Baseline and Week 16	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much (score of 3), a lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired.	Baseline, Week 16
Dermatology Life Quality Index (DLQI) Categories at Week 4	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much (score of 3), a	Week 4

	lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired. The following scoring categories present the effect on participant s life: 0-1 no effect at all; 2-5 small effect; 6-10 moderate effect; 11-20 very large effect; 21-30 extremely large effect.	
Dermatology Life Quality Index (DLQI) Categories at Week 16	Dermatology Life Quality Index (DLQI) score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much (score of 3), a lot, a little, or not at all (score of 0). The DLQI score ranges from 0 (best) to 30 (worst); the higher the score, the more quality of life is impaired. The following scoring categories present the effect on participant s life: 0-1 no effect at all; 2-5 small effect; 6-10 moderate effect; 11-20 very large effect; 21-30 extremely large effect.	Week 16
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI)-50, 90, 100 Responses at Week 4	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI-50, 90, and 100 responses are the percentage of participants who achieved at least a 50%, 90%, or 100% reduction (improvement) from baseline in PASI score at Week 4. 100% reduction was considered complete clearance of psoriasis.	Week 4
Percentage of Participants	PASI is a composite score based on the degree of effect on body surface area of psoriasis and	Week 16

Achieving Psoriasis Area and Severity Index (PASI)-50, 90, 100 Responses at Week 16	the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI-50, 90, and 100 responses are the percentage of participants who achieved at least a 50%, 90%, or 100% reduction (improvement) from baseline in PASI score at Week 4. 100% reduction was considered complete clearance of psoriasis.	
Physicians Global Assessment (PGA) at Week 4	The PGA is a 7-point scale used to measure the severity of disease at the time of the physicians evaluation of the participant. Categories are as follows: Severe = very marked plaque elevation, scaling, and/or erythema; Moderate to severe = marked plaque elevation, scaling, and/or erythema; Moderate = moderate plaque elevation, scaling, and/or erythema; Mild to moderate = intermediate between moderate and mild; Mild = slight plaque elevation, scaling, and/or erythema; Almost clear = intermediate between mild and clear; Clear = no signs of psoriasis (post-inflammatory hypopigmentation or hyperpigmentation could be present).	Week 4
Physicians Global Assessment (PGA) at Week 16	The PGA is a 7-point scale used to measure the severity of disease at the time of the physicians evaluation of the participant. Categories are as follows: Severe = very marked plaque elevation, scaling, and/or erythema; Moderate to severe = marked plaque elevation, scaling, and/or erythema; Moderate = moderate plaque elevation, scaling, and/or erythema; Mild to moderate = intermediate between moderate and mild; Mild = slight plaque elevation, scaling, and/or erythema; Almost clear = intermediate between mild and clear; Clear = no signs of psoriasis (post-inflammatory hypopigmentation	Week 16

	or hyperpigmentation could be present). The number of participants who achieve a PGA of clear or almost clear at Week 16 was a secondary outcome measure in this study.	
Mean Lipid Profile, Triglycerides, and C-Reactive Protein (CRP) at Baseline and Week 16	Normal values: C-reactive protein (CRP) 0-0.79 mg/dL; cholesterol 30-199 mg/dL; high density lipoprotein (HDL) 40-100 mg/dL; very low density lipoprotein (VLDL) 0-34 mg/dL; low density lipoprotein (LDL) 20-99 mg/dL; triglycerides 50-149 mg/dL.	Baseline, Week 16
Mean Homocysteine Levels at Baseline and Week 16	Normal values for homocysteine were 5-13.9 µmol/L.	Baseline, Week 16
Percentage of Obese vs. Non-obese (Per Body Mass Index [BMI]) Participants Achieving a Psoriasis Area and Severity Index (PASI)-75 Response and a Total Dermatology Life Quality Index (DLQI) Score of <6 at Week 16	The Body Mass Index (BMI) was used to determine the groups of participants who were overweight and who were considered obese. A BMI of 18.5 to 25 was considered normal range, 25 to 30 as overweight and 30 and above as obesity, in both men and women. Response to treatment in participants with obesity (based on Body Mass Index) versus those without obesity was assessed via PASI-75 response (see Outcome Measure 1 for details) and DLQI score of <6 (see Outcome Measure 3 for details).	Week 16
Percentage of Obese vs. Non-obese (Per	The Waist-Hip Ratio was used to determine the groups of participants who were overweight and who were considered obese. Obesity was	Week 16

Waist-Hip Ratio) Participants Achieving a Psoriasis Area and Severity Index (PASI)-75 Response and a Total Dermatology Life Quality Index (DLQI) Score of <6 at Week 16	defined as a ratio of >1 for men and >0.8 for women. Response to treatment in participants with obesity (based on Waist-Hip Ratio) versus those without obesity was assessed via PASI-75 response (see Outcome Measure 1 for details) and DLQI score of <6 (see Outcome Measure 3 for details).	
Serum Levels of Folic Acid at Baseline and Week 4	Normal values for folic acid were 3-15 ng/mL.	Baseline, Week 4
Serum Levels of Vitamin B6 at Baseline and Week 4	Normal values for vitamin B6 were 18-175 nmol/L.	Baseline, Week 4
Serum Levels of Vitamin B12 at Baseline and Week 4	Normal values for vitamin B12 were 200-1100 pg/mL.	Baseline, Week 4
Serum Levels of Folic Acid at Baseline and Week 16	Normal values for folic acid were 3-15 ng/mL.	Baseline, Week 16
Serum Levels of Vitamin B6 at Baseline and Week 16	Normal values for vitamin B6 were 18-175 nmol/L.	Baseline, Week 16

Serum Levels of Vitamin B12 at Baseline and Week 16	Normal values for vitamin B12 were 200-1100 pg/mL.	Baseline, Week 16

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

No information provided

Investigators

- Study Director: Jose Luis Canadas, Medical Director, MD, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of

Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-12-22

First Submitted that Met QC Criteria
2010-12-22

First Posted (Estimated)
2010-12-23

Results Reporting Dates

Results First Submitted
2013-02-01

Results First Submitted that Met QC Criteria
2013-02-01

Results First Posted (Estimated)
2013-03-11

Study Record Updates

Last Update Submitted that met QC Criteria
2013-02-01

Last Update Posted (Estimated)
2013-03-11

Last Verified
2013-02

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Humira
Adalimumab
Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related info (http://rxabbvie.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Comparison of 122-0551 Foam Versus Vehicle Foam in Subjects With Plaque Psoriasis (Study 310)

ClinicalTrials.gov ID NCT02742441

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2018 11 14

Study Details Tab

Study Overview

Brief Summary

This Phase 3 study (Study 310) has been designed to determine and compare the efficacy and safety of 122 0551 Foam and Vehicle Foam applied twice daily for two weeks in subjects with plaque psoriasis.

Feedback

Official Title

A Multicenter, Randomized, Double Blind, Parallel Group Comparison of 122 0551 Foam Versus Vehicle Foam in Subjects With Plaque Psoriasis (Study 310)

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: 122 0551 Foam
- Drug: Vehicle Foam

Other Study ID Numbers

- 122 0551 310

Study Start

2016 06

Primary Completion (Actual)

2017 02 27

Study Completion (Actual)

2017 06 16

Enrollment (Actual)

409

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arkansas Locations

Fort Smith, Arkansas, United States, 72916
Site 14

Hot Springs, Arkansas, United States, 71913
Site 01

California Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subject is male or non pregnant female and is at least 18 years of age at the time of the Screening Visit.
2. Subject has provided written informed consent.
3. Subject is willing and able to apply the test article(s) as directed, comply with study instructions and commit to all follow up visits for the duration of the study.
4. Subject has a clinical diagnosis of stable plaque psoriasis involving a minimum of 2% and no more than 12% body surface area (BSA) (excluding the face, scalp, groin, axillae and other intertriginous areas).
5. Subject has an Investigator s Global Assessment (IGA) score of at least three (3 = moderate) at the Baseline Visit.
6. Females must be post menopausal , surgically sterile or use an effective method of birth control , with a negative urine pregnancy test (UPT) at the Baseline Visit.

Exclusion Criteria:

1. Subject has spontaneously improving or rapidly deteriorating plaque psoriasis.
2. Subject has guttate, pustular, erythrodermic or other non plaque forms of psoriasis.
3. Subject has a physical condition which, in the investigator s opinion, might impair evaluation of plaque psoriasis, or which exposes the subject to an unacceptable risk by study participation.
4. Subject has used any phototherapy (including laser), photo chemotherapy or other forms of photo based therapy for the treatment of their psoriasis within 30 days prior to the Baseline Visit.
5. Subject has used any systemic methotrexate, retinoids, systemic corticosteroids [including intralesional, intra articular, and intramuscular corticosteroids], cyclosporine or analogous products within 90 days prior to the Baseline Visit.
6. Subject has used any systemic biologic therapy (i.e., FDA approved or experimental therapy) within five (5) half lives of the biologic prior to the Baseline Visit. Published or documented half life of the product provided by the commercial supplier or Sponsor should be used to establish this value.
7. Subject had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to the Baseline Visit or is intending to have such exposure during the study which in the opinion of the investigator is thought to modify the subject s disease.
8. Subject has used topical body (excluding the scalp) psoriasis therapy (including coal tar, anthralin, steroids, retinoids and vitamin D analogs) within 14 days prior to the Baseline Visit.
9. Subject has used emollients/moisturizers on areas to be treated within four hours prior to clinical evaluation at the Baseline Visit.
10. Subject is currently using lithium or Plaquenil (hydroxychloroquine).
11. Subject is currently using a beta blocking medication (e.g., propranolol) or angiotensin converting enzyme (ACE) inhibitor at a dose that has not been stabilized, in the opinion

of the investigator.

12. Subject has a history of sensitivity to any of the ingredients in the test articles.
13. Subject is pregnant, lactating, or is planning to become pregnant during the study.
14. Subject is currently enrolled in an investigational drug or device study.
15. Subject has used an investigational drug or investigational device treatment within 30 days prior to the Baseline Visit.
16. Subject has been previously enrolled in this study and treated with a test article.
17. Subject is known to be noncompliant or is unlikely to comply with the requirements of the study protocol (e.g., due to alcoholism, drug dependency, mental incapacity) in the opinion of the investigator.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 122-0551 Foam 122-0511 Foam, topically applied twice daily Intervention: Drug: 122-0551 Foam	Drug: 122-0551 Foam • Topical Foam containing active drug
Placebo Comparator: Vehicle Foam Vehicle Foam, topically applied twice daily Intervention: Drug: Vehicle Foam	Drug: Vehicle Foam • Topical Foam containing no active drug

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Rated a "Treatment Success" Based on the Investigator s Global	The IGA score is a static evaluation of the overall or "average" degree of severity taking into account all of the subject s psoriatic lesions in the Treatment Area by the investigator or designee. This evaluation takes into consideration the three individual characteristics of psoriasis (scaling, erythema and plaque elevation) with the IGA score at each visit	Day 15

Assessment (IGA)	representing the average of scaling, erythema or plaque elevation that is present amongst all of the lesions eligible for treatment. IGA will be assessed on a 5-point scale where 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling, Erythema and Plaque Elevation)	Scaling, erythema and plaque elevation will each be scored on a 5-point scale where 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe. These evaluations are an assessment of the overall or "average" degree of each of three key characteristics present within all of the subject s psoriatic lesions in the Treatment Area by the investigator or designee.	Day 15

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Rated a "Treatment Success" Based on the Investigator s Global Assessment (IGA)		Day 8

Percentage of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling, Erythema and Plaque Elevation)		Day 8
Change From Baseline in Pruritus Score	At the Baseline Visit, prior to the first application of the test article, the subject s overall experience of pruritus within the previous two (2) weeks will be assessed and scored (range 1-5) using a questionnaire that assesses the degree, duration, direction, disability, and distribution of the subject s pruritus. Possible total scores range from 5 (no pruritus) to 25 (most severe pruritus). At Day 15, the overall experience of pruritus, in the previous two weeks, will be scored using the same questionnaire.	Day 15
Changes in Percent BSA With Active Psoriasis in the Treatment Area	The percent (%) Body Surface Area (BSA) with active psoriasis in the Treatment Area will be determined at the Baseline Visit and Week 2 (Day 15) and documented. At Baseline, the percent BSA with active psoriasis in the Treatment Area must be 2% to 12%, inclusive.	Day 15

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Therapeutics, Inc.

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2016-04-14

First Submitted that Met QC Criteria
2016-04-14

First Posted (Estimated)
2016-04-19

Results Reporting Dates

Results First Submitted
2018-09-17

Results First Submitted that Met QC Criteria
2018-10-16

Results First Posted
2018-11-14

Study Record Updates

Last Update Submitted that met QC Criteria
2018-10-16

Last Update Posted
2018-11-14

Last Verified
2018-10

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

Drug and device information, study documents, and helpful links

Study Documents

- Study Protocol and Statistical Analysis Plan (https://storage.googleapis.com/ctgov2_large docs/41/NCT02742441/Prot_SAP_000.pdf) [PDF, 3.28MB, 2016 06 17]

Record 1 of 1

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COMPLETED

Paired Psoriasis Lesion, Comparative, Study to Evaluate MOL4239 in Psoriasis

ClinicalTrials.gov ID NCT01826201

Sponsor Moleculin, LLC

Information provided by Moleculin, LLC (Responsible Party)

Last Update Posted 2014 12 24

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study is to determine whether MOL4239 is effective in adult subjects with mild to moderate plaque psoriasis by comparing two target lesions in which each subject will apply MOL4239 ointment to one target lesion and placebo ointment to the contralateral target lesion twice a day for 28.5 consecutive days.

Detailed Description

This is a phase 2a, Randomized, Multi center, Blinded, Paired Psoriasis Lesion, Comparative Placebo Controlled study to evaluate the safety, preliminary efficacy and pharmacokinetics of MOL4239 in 30 adult subjects with mild to moderate plaque psoriasis. Eligible subject will have a diagnosis of mild to moderate plaque psoriasis affecting 9.9% body surface area (BSA) or less, and two designated similar target lesions with a Psoriasis Severity Score of at least 6 or higher. Each subject will apply 10% MOL4239 ointment to one target lesion and placebo ointment to the contralateral target lesion twice a day for 28.5 consecutive days.

Official Title

A Phase 2a, Randomized, Blinded, Paired Psoriasis Lesion, Comparative, Placebo controlled Study to Evaluate the Safety, Preliminary Efficacy and Pharmacokinetics of Epidermal Administrations of MOL4239 in Adults With Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: MOL4239
- Drug: Placebo

Other Study ID Numbers

- M 02

Study Start

2013 03

Primary Completion (Actual)

2013 08

Study Completion (Actual)

2013 08

Enrollment (Actual)

21

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Birthmarks (https://medlineplus.gov/birthmarks.html) Moles (https://medlineplus.gov/moles.html) Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Florida Locations

Miami, Florida, United States, 33144
International Dermatology Research, Inc.

Minnesota Locations

Fridley, Minnesota, United States, 55432
Minnesota Clinical Study Center

New Mexico Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Adults, males or females, 18 to 72 years of age (both inclusive.)
- Mild to moderate plaque psoriasis with lesions that in total are no more than 9.9% BSA and with a baseline Psoriasis Severity Score (PSS) of 6 or more.
- Identification of bilaterally symmetrical or approximately equivalent target lesions of at least 2.5 x 2.5 cm (~6 cm2) on the trunk, arms or legs to mid calf with a Psoriasis Severity Score (PSS) of 6 or greater.
- Willing to avoid tanning devices or exposure of the treated skin to the sun.
- Willing to not use cosmetics, including lotions, creams, and moisturizers on the treated lesions.
- Use of Eucerin® is allowed on all non test site areas.
- Willing to forgo systemic and other topical treatments for psoriasis during the course of the study.
- Willing to avoid bathing or swimming for two hours after study drug treatment.
- Negative urine pregnancy test at Screening and baseline for women of childbearing potential (WOCP).
- Sexually active WOCP participating in the study must agree to use a medically acceptable method of contraception while on study.
- Must have recovered from the effects of any surgery, other than minor office surgical procedures, and a minimum of 3 months must have elapsed from the day of surgery to the day of screening.

Exclusion Criteria:

- Presence of significant abnormalities of liver or renal functions.
- Presence of any clinically significant lab abnormalities at screening.
- Any significant uncontrolled medical disease.
- Use of the anti tumor necrosis factor (TNF) biologic agents 4 months prior to randomization or use of Stelara 6 months prior to randomization.
- Use, within one month prior to baseline or during the study, of: 1) systemic immunosuppressive drugs (e.g., tacrolimus), or 2) oral meds (e.g. methotrexate, retinoids, etc.).
- Use within one month prior to baseline or during the study of: 1) Systemic corticosteroids, 2) Systemic antibiotics, 3) other systemic antipsoriatic treatment, 4) oral psoralen with ultraviolet A (PUVA) therapy, or 5) ultraviolet B (UVB) therapy.
- Use within two weeks prior to baseline or during the study of: 1) topical anti psoriatic drugs, 2) topical corticosteroids, 3) other topical retinoids, or 4) topical immunosuppressive agents.
- Current diagnosis of unstable forms of psoriasis in the treatment area, including guttate, erythrodermic, exfoliative or pustular psoriasis.
- Other inflammatory skin disease in the treatment area that may confound the evaluation of the psoriasis vulgaris.
- Females who are pregnant, breast feeding, or planning a pregnancy.

Ages Eligible for Study

18 Years to 72 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : Double (Participant, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 10% MOL4239 ointment & placebo ointment 10% MOL4239 ointment to one target lesion and placebo ointment to the contralateral target lesion twice a day for 28.5 consecutive days	Drug: MOL4239 • 10% MOL4239 ointment to one target lesion twice a day for 28.5 consecutive days Drug: Placebo • placebo ointment to the contralateral target lesion twice a day for 28.5 consecutive days

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Change From Baseline to Day 28 in PSS (Psoriasis Severity Score) of the Treatment Target Lesions Compared to Placebo Target Lesions	he study drug application sites were scored for erythema, induration, and scale assessment using the PSS Scoring system. Psoriasis Severity Score (PSS) Erythema 0 - 4, 0 None, may have residual non-erythematous discoloration 1 Faint erythema 2 Moderate erythema/red color 3 Severe erythema/very red discoloration 4 Very severe erythema/extreme red coloration Induration 0 - 4 0 None 1. Trace or slight elevation of plaque above normal skin level 2. Moderate elevation with rounded or sloped edges to plaque	Baseline and Day 28

	3. Marked elevation with hard, sharp edges to plaque 4. Very marked elevation with very hard, sharp edges to plaque Scaling 0 - 4 0 None 1. Fine scales 2. Coarse scales 3. Thick scales with a rough surface 4. Thick scales with a very rough surface The scores were summed	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Improvement in Lesion Appearance	Photography of the MOL4239 and placebo treated lesions will be performed at baseline, Day 7, Day 14 and Day 28 to assess for the improvement in lesion appearance after drug treatment. The assessment will be completed by a blinded panel of dermatologists experienced in the assessment of psoriasis.	Baseline and Day 28
Physicians Treatment Preference	The physicians treatment preference utilizing visual assessment and selection of the most improved plaque. The determination will be either 1)right lesion is preferred compared to left, 2)left lesion is preferred compared to right, 3) no difference between the right and left lesion.	Day 7, Day 14, Day 28
Treatment Success	Percent of patients achieving treatment success in the treatment group compared to the placebo group on day 28. Treatment success is defined as patient achieving a psoriasis severity score (PSS) of 3 or less, or an improvement of 5 points or more on the PSS.	Baseline and Day 28

Change in EIS Area	Change in Erythema, Induration and Scale (EIS) area. Total score will be the EIS x Area, and will be calculated at baseline, Day 7, Day 14 and Day 28. The EIS will represent the sum of individual scores of Erythema, Induration and Scale using the same scale utilized in the PSS. The area of active erythema, induration and scale will be measured and the total scores will be calculated from the EIS scores multiplied by the area in cm2.	Baseline and Day 28
Safety Assessment	Safety will be assessed based on reported adverse events, physical examination, vital signs, electrocardiograms, hematology, serum chemistry and urinalysis. Adverse events will be reported throughout the trial. Vital signs will be performed at screening, baseline, prior to the morning dose on Days 0, 1, 7, 14, 28, and at the follow up visit on Day 42. Physical examinations will be performed at Screening, baseline and Day 28. Hematology, serum chemistry and urinalysis will be performed at screening, baseline, Days 1, 7, 14, 28, and at the follow up visit on Day 42. ECGs will be performed at Screening, baseline and Day 28.	Baseline and Day 28

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Moleculin, LLC

Collaborators

No information provided

Investigators

- Principal Investigator: Eduardo Tschen, MD, Academic Dermatology Associates

- Principal Investigator: Javier Alonso Llamazares, MD, International Dermatology Research, Inc.
- Principal Investigator: Steven Kempers, MD, Minnesota Clinical Study Center

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-03-21

First Submitted that Met QC Criteria
2013-04-03

First Posted (Estimated)
2013-04-08

Results Reporting Dates

Results First Submitted
2014-11-11

Results First Submitted that Met QC Criteria

2014-12-22

Results First Posted (Estimated)

2014-12-24

Study Record Updates

Last Update Submitted that met QC Criteria

2014-12-22

Last Update Posted (Estimated)

2014-12-24

Last Verified

2014-12

More Information

Terms related to this study

Keywords Provided by Moleculin, LLC

psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Study of the Clinical Activity, Safety, and Tolerability of SRT2104 in Subjects With Moderate to Severe Plaque-Type Psoriasis

ClinicalTrials.gov ID NCT01154101

Sponsor Sirtris, a GSK Company

Information provided by GlaxoSmithKline (Sirtris, a GSK Company) (Responsible Party)

Last Update Posted 2017 10 13

Study Details Tab

Study Overview

Brief Summary

This double blind, placebo controlled study will be conducted at 5 study centers in the United States. Approximately 30 subjects with moderate to severe plaque type psoriasis will take part. The study will consist of a screening period of up to 21 days, a 12 week treatment period with 7 on treatment

Feedback

clinic visits (approximately one every 2 weeks) and a post dosing follow up clinic visit approximately 30 days after the last dose of study drug is taken.

Subjects will be randomized to receive either 250mg, 500mg or 1000mg of study drug or placebo. Study drug will be taken by mouth on a full stomach, every day for 84 days.

Vital signs, clinical laboratory results (hematology, chemistry, and urinalysis), ECGs and physical examinations will be assessed at periodic intervals from Day 1 through Day 84.

A skin biopsy will be taken at the beginning and the end of the dosing period to evaluate any effects of the study drug on psoriasis. Investigators will perform other psoriasis evaluations (including the Psoriasis Area and Severity Index [PASI] and the Physicians Global Assessment [PGA] at 5 different times throughout the study to quantify the effects of SRT2104 on psoriasis activity.

Subjects will complete questionnaires throughout the study, to document their sense of well being and mood at 4 different times during the study.

Five blood samples will be obtained at different timepoints during the study, to measure the amount of SRT2104 in the body.

Official Title

A Randomized, Double Blind, Placebo Controlled, Phase IIa Study of the Clinical Activity, Safety, and Tolerability of SRT2104 in Subjects With Moderate to Severe Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Placebo
- Drug: SRT2104

Other Study ID Numbers

- 114296

Study Start (Actual)

2010 06 07

Primary Completion (Actual)

2011 11 09

Study Completion (Actual)

2011 11 09

Enrollment (Actual)

40

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Missouri Locations

Saint Louis, Missouri, United States, 63117
GSK Investigational Site

New York Locations

New York, New York, United States, 10016
GSK Investigational Site

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Able and willing to provide written informed consent to participate in the study
- Be male or female aged 18 to 80 years (inclusive)
- Have a diagnosis of clinically confirmed, stable (without recent documented flare within 30 days prior to the Screening Visit), plaque type psoriasis for at least 6 months involving ≥10% of body surface area
- Have a baseline PASI of ≥10
- Be a candidate for systemic psoriasis therapy, in the opinion of the investigator
- If a female subject of child bearing potential, be willing to use reliable contraception for the duration of the study, through the 30 day safety follow up telephone call
- Be willing and able to comply with the protocol for the duration of the study

Exclusion Criteria:

- Has received systemic non biologic psoriasis therapy or PUVA phototherapy within 4 weeks prior to the Screening Visit, or had topical psoriasis treatment or UVB phototherapy within 2 weeks prior to the Screening Visit
- Has received previous treatment with biologic agents within 5 drug half lives (or within 3 months if half life is unknown) prior to the first dose of SRT2104
- Has received a live vaccination within 4 weeks prior to the Screening Visit or intends to have a live vaccination during the course of the study
- Use of any other non psoriatic prescription drug therapy, with the exception of any prescription medication administered at a stable dose for at least 6 weeks prior to the Screening Visit; however, the administration of proton pump inhibitors during the study dosing period is prohibited
- Use of any dietary or herbal supplements, with the exception of those administered at a stable dose for at least 6 weeks prior to the Screening Visit
- Has received any investigational drug or experimental procedure within 30 days prior to the first dose of SRT2104
- Has an active infection (e.g., sepsis, pneumonia, abscess, etc.) or be at high risk of developing an infection, in the opinion of the investigator, prior to the first dose of SRT2104
- Has a history of a positive tuberculosis test or a positive tuberculosis test at the Screening Visit that cannot be attributed to a prior BCG inoculation
- Has a positive pre study Hepatitis B surface antigen or positive Hepatitis C antibody result within 3 months of the Screening Visit
- Has a positive test for HIV antibody
- Has an abnormal chest x ray at the Screening Visit which, in the opinion of the investigator, would preclude entry into the trial
- Has a 12 lead electrocardiogram (ECG) with changes considered to be clinically significant on medical review including prolonged QTc intervals as defined below:
- QTcB ≥450 msec (based on single or average QTc value of triplicate ECGs obtained over a brief period)

- QTcB ≥480 msec in subjects with Bundle Branch Block
- Has renal or liver impairment, defined as:
- Serum creatinine level of ≥ 1.4 mg/dL for females and ≥ 1.5 mg/dL for males
- AST and ALT ≥ 2xULN or
- Alkaline phosphatase and bilirubin > 1.5xULN (an isolated bilirubin >1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin is <35%)
- Has active neoplastic disease or history of neoplastic disease within 5 years of study entry (except for basal or squamous cell carcinoma of the skin, or carcinoma in situ which have been definitively treated with standard of care approaches)
- Is pregnant or breast feeding. Confirmation that a female subject is not pregnant must be established by negative pregnancy tests at Screening and Day 1
- Has a significant history of alcoholism or drug/chemical abuse, or consumes more than 3 standard units/day of alcohol. A standard unit of alcohol is defined as 250 mL of beer, 25 mL of spirit, or 125 mL of wine
- History of sensitivity to any of the study medications, or components thereof, or a history of drug or other allergy that, in the opinion of the investigator or medical monitor, contraindicates their participation
- Has an acute or chronic illness which, in the opinion of the investigator, could pose a threat or harm to the subject

Ages Eligible for Study

18 Years to 80 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Cohort 2 - 500mg SRT2104/placebo dose group 10 subjects will be randomized 4:1 (SRT2104: placebo) in each of 3 treatment arms (250mg, 500mg, or 1000mg). Cohort 2 will commence after Cohort 1 has completed 28 consecutive days of dosing, followed by the completion of a safety review by an Independent Safety Review Committee. Cohort 2 will be administered at approximately the same time every day, approximately 15 minutes following the consumption of food. Subjects must wait at least 1 hour after dosing before consuming additional calories. Dietary recommendations for	Drug: Placebo • For the placebo product, the SRT2104 drug substance will be replaced by microcrystalline cellulose (Avicel® PH 105) to match the SRT2104 investigational product. Drug: SRT2104 • SRT2104 drug substance is a new chemical entity which is supplied as a fine, yellowish/amber powder. The SRT2104 investigational product is prepared by packing 250 mg of micronized SRT2104 powder with no additional additives into a size 00 opaque, hard gelatin capsule, packaged in dosing bottles containing a single daily dose.

the meal that precedes dosing will be provided to the study subjects by the clinical site staff.	
Active Comparator: Cohort 3 - 1000mg SRT2104/placebo dose group 10 subjects will be randomized 4:1 (SRT2104: placebo) in each of 3 treatment arms (250mg, 500mg, or 1000mg). Cohort 3 will commence after Cohort 2 has completed 28 consecutive days of dosing, followed by the completion of a safety review by an Independent Safety Review Committee. Cohort 3 will be administered four SRT2104 capsules at approximately the same time every day, approximately 15 minutes following the consumption of food. Subjects must wait at least 1 hour after dosing before consuming additional	Drug: Placebo • For the placebo product, the SRT2104 drug substance will be replaced by microcrystalline cellulose (Avicel® PH 105) to match the SRT2104 investigational product. Drug: SRT2104 • SRT2104 drug substance is a new chemical entity which is supplied as a fine, yellowish/amber powder. The SRT2104 investigational product is prepared by packing 250 mg of micronized SRT2104 powder with no additional additives into a size 00 opaque, hard gelatin capsule, packaged in dosing bottles containing a single daily dose.

calories. Dietary recommendations for the meal that precedes dosing will be provided to the study subjects by the clinical site staff.	
Active Comparator: Cohort 1 - 250mg SRT2104/placebo dose group 10 subjects will be randomized 4:1 (SRT2104: placebo) in each of 3 treatment arms (250mg, 500mg, or 1000mg). Cohort 1 will be administered at approximately the same time every day, approximately 15 minutes following the consumption of food. Subjects must wait at least 1 hour after dosing before consuming additional calories. Dietary recommendations for the meal that precedes dosing will be provided to the study subjects by the clinical site staff. Dosing for Cohort 2 will not commence	Drug: Placebo • For the placebo product, the SRT2104 drug substance will be replaced by microcrystalline cellulose (Avicel® PH 105) to match the SRT2104 investigational product. Drug: SRT2104 • SRT2104 drug substance is a new chemical entity which is supplied as a fine, yellowish/amber powder. The SRT2104 investigational product is prepared by packing 250 mg of micronized SRT2104 powder with no additional additives into a size 00 opaque, hard gelatin capsule, packaged in dosing bottles containing a single daily dose.

until Cohort 1 has completed 28 consecutive days of dosing, followed by the completion of a safety review by an Independent Safety Review Committee.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Assessment of Clinical Activity by Improvement Score (Using Krueger Criteria): Number of Participants With Good or Excellent Improvement Score Based on Histological Assessments of Skin Biopsies After 12 Weeks of Exposure	According to the Krueger criteria, improvement score is classified as Good improvement defined as reduction in epidermal thickness by at least 30% normalized keratinocyte differentiation but most keratinocytes still express K16. Excellent improvement defined as reduction in epidermal thickness to normal or almost normal normalized keratinocyte differentiation and absent keratinocyte expression of K16. No improvement defined as no improvement in epidermal thickness keratinocyte differentiation or K16 expression on keratinocytes. A binomial response was defined for each participant according to whether the participant had an improvement score of "good or excellent improvement" (response=1) or not (response=0). Number of participants with good or excellent improvement score are presented.	12 weeks

Number of Participants With Any Adverse Events (AE) and Serious Adverse Events (SAE)	An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse. SAE is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect or is medically significant. The AE category in the data table includes participants who experienced serious or non-serious adverse events or both.	Up to Follow-up (Day 114)
Number of Participants With Hematology and Coagulation Abnormalities of Potential Clinical Concern	Hematology parameters included hemoglobin, hematocrit, red blood cell count, red cell distribution width, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, platelets, white blood cell count and complete white blood cell count differential. Coagulation parameters included activated partial thromboplastin time and prothrombin time/international normalized ratio. The potential clinical concern range for hematology parameters were: white blood cell count (low: <0.67x10^9/Liter x lower limit of normal [LLN] and high: >1.82x10^9/L x upper limit of normal [ULN]), neutrophil count: (low: <0.83x10^9/Liter x LLN), hemoglobin (low: <0.85 gram/Liter x LLN and high: >1.03 gram/Liter x ULN for males and >1.13 gram/Liter x ULN for females),	Up to Follow-up (Day 114)

	hematocrit with units ratio (high: >1.02 x ULN for males and >1.17 x ULN for females), platelet count (low: <0.67x10^9/Liter x LLN and high >1.57x10^9/Liter x ULN) and lymphocytes (low: <0.81x10^9/Liter x LLN).	
Number of Participants With Clinical Chemistry Abnormalities of Potential Clinical Importance	The potential clinical concern range for clinical chemistry parameters were: Albumin:(low: <0.86 gram/Liter x LLN), Calcium:(low: <0.91 millimol/Liter [mmol/L] x LLN and high: >1.06 mmol/L x ULN), Creatinine: (high: >1.3 mmol /L x ULN), Glucose: (low: <0.71 mmol/L x LLN, high: >1.41 mmol/L x ULN), Magnesium: (low: <0.63 mmol/L x LLN, high: >1.03 mmol/L x ULN), Phosphorus: (low: <0.8 mmol/L x LLN, high: >1.14 mmol/L x ULN), Sodium: (low: <0.96 mmol/L x LLN, high: >1.03 mmol/L x ULN), Urea: (high: >1.5 mmol/L x ULN), Gamma glutamyl transferase: (high: >2 International units per L x ULN), Total bilirubin (high: 1.5 x ULN), both alanine amino transferase and aspartate amino transferase (high:≥ 2x ULN Units/L) and Bicarbonate: (low: <18 mmol/L and high: >32 mmol/L). Number of participants with clinical chemistry abnormalities of potential clinical importance are presented.	Up to Follow-up (Day 114)
Number of Participants With Abnormal Electrocardiogram (ECG) Values	12-lead ECG was performed in the rested state with the participant in the supine position with ECG leads on for at least 5 minutes prior to ECG recording. ECGs included PR (PQ), QRS, QT and QT corrected by Bazett s formula (QTcB), QT corrected by Fridericia s formula (QTcF) intervals. Identification of any conduction abnormalities were recorded in the eCRF. If a participant s QTc intervals were prolonged, then the ECG was done in triplicate with results reported as an average of the three ECGs. Number of participants with abnormal electrocardiogram (ECG) values are presented.	Up to Follow-up (Day 114)

Number of Participants With Vital Signs of Potential Clinical Importance	Vital sign assessments included measurements of resting heart rate and blood pressure. Potential clinical concern range for systolic blood pressure: <85 and >160 millimeter of mercury (mmHg), for diastolic: <45 and >100 mmHg and heart rate: <40 and >110 beats per minute. Number of participants with vital signs of potential clinical importance are presented.	Up to Follow-up (Day 114)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Clinical Activity in Psoriasis Area and Severity Index (PASI) Score After 4, 8, and 12 Weeks of Exposure	PASI score was determined by evaluation of body surface area (BSA) covered by plaque psoriasis in 4 areas (head/neck, arms, trunk and legs with area score of 0.1, 0.2, 0.3 and 0.4 respectively). This test included combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale such that 0=0% involvement, 1=1-9%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0=No evidence of sign, 1=slight evidence, 2=moderate evidence, 3=marked evidence and 4=very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same 4 areas. PASI score ranges from 0 (no psoriasis) to 72 (worse psoriasis). Final PASI= (sum of severity score for each area)x(% body affected score x area score).	Weeks 4, 8 and 12
Summary of Physicians Global Assessment (PGA) Score After	The severity of psoriatic lesions over the whole body were assessed by the investigator using the PGA scoring system. A 0 to 6 point rating scale was used, as follows: 0 = Clear	Weeks 4, 8 and 12

4, 8 and 12 Weeks of Exposure	(no signs of psoriasis), 1 = Almost clear (slight elevation, scale and/or erythema), 2 = Mild (mild plaque elevation, scale and/or erythema), 3 = Mild to moderate (mild plaque elevation with moderate erythema and/or scale), 4 = Moderate (moderate plaque elevation, scale and/or erythema), 5 = Moderate to severe (marked plaque elevation, scale and/or erythema), 6 = Severe (very marked plaque elevation, scale and/or erythema). Higher scores indicated worse psoriasis. Participants in the SRT2104 0.25 g dose group inadvertently used an incorrect version of the PGA scale and thus do not have PGA data available. Participants in the SRT2104 0.25 g dose group inadvertently used an incorrect version of the PGA scale and thus do not have PGA data available.	
Area Under Curve (AUC) of 12 Weeks of Dosing With 0.25 g, 0.5 g and 1.0 g SRT2104 in the Fed State in Participants	A total of five blood samples (6 milliliter [mL] each) were obtained from each participant up to Week 12, for determination of SRT2104 plasma concentrations. No two samples were separated by less than an hour. One pre-dose sample was collected prior to taking study medication (30 minutes or less before dosing) at any Visit 4 (Week 4), Visit 6 (Week 8) or Visit 8 (Week 12). A single pharmacokinetic (PK) sample was collected in the time interval of 0.5 to 2 hours post-dose and also 3 to 6 hours post-dose at any Visit 4 (Week 4), Visit 6 (Week 8) or Visit 8 (Week 12). Two PK samples were collected in the time interval of 6 to 22 hours post dose at any Visit 4 (Week 4), Visit 6 (Week 8) or Visit 8 (Week 12).	Pre-dose (30 minutes or less before dosing: 1 sample), 0.5 to 2 hours and 3 to 6 hours post-dose (1 sample), 6 to 22 hours post-dose (2 samples) up to Week 12

Maximum Plasma Concentration (Cmax) of 12 Weeks of Dosing With 250 Milligrams (mg), 500 mg and 1000 mg SRT2104 in the Fed State in Participants	A total of five blood samples (6 mL each) were obtained from each participant at any Visit 4 (Day 28 or Week 4), Visit 6 (Day 56 or Week 8) or Visit 8 (Day 84 or Week 12), for determination of SRT2104 plasma concentrations. No two samples were separated by less than an hour. One pre-dose sample was collected prior to taking study medication (30 minutes or less before dosing) at any Visit 4 (Day 28 or Week 4), Visit 6 (Day 56 or Week 8) or Visit 8 (Day 84 or Week 12). A single pharmacokinetic (PK) sample was collected in the time interval of 0.5 to 2 hours post-dose and also 3 to 6 hours post-dose at any Visit 4 (Day 28 or Week 4), Visit 6 (Day 56 or Week 8) or Visit 8 (Day 84 or Week 12). Two PK samples were collected in the time interval of 6 to 22 hours post dose at any Visit 4 (Day 28 or Week 4), Visit 6 (Day 56 or Week 8) or Visit 8 (Day 84 or Week 12).	One sample: Pre-dose (30 minutes or less before dosing), One sample: 0.5 to 2 hours post-dose and 3 to 6 hours post-dose and 2 samples 6 to 22 hours post dose, at any Visit 4 (Day 28 or Week 4), Visit 6 (Day 56 or Week 8) or Visit 8 (Day 84 or Week 12)
Change From Baseline in Fibroblast Growth	The pharmacodynamic effects of SRT2104 was measured by biomarkers of psoriatic disease activity and/or sirtuin pathway	Baseline (Day 1) and Days

Factor 21 (FGF21) as an Indicator of the Pharmacodynamic Effects of SRT2104	activation (hsCRP and FGF21) in blood samples. Baseline was Day 1. Change from Baseline was calculated by subtracting Baseline values from post-Baseline values.	28, 56 and 84
Change From Baseline in High-sensitivity C-reactive Protein (hsCRP) as an Indicator of the Pharmacodynamic Effects of SRT2104	The pharmacodynamic effects of SRT2104 was measured by biomarkers of psoriatic disease activity and/or sirtuin pathway activation (hsCRP and FGF21) in blood samples. Baseline was Day 1. Change from Baseline was calculated by subtracting Baseline values from post-Baseline values.	Baseline (Day 1) and Days 28, 56 and 84

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Sirtris, a GSK Company

Collaborators

- GlaxoSmithKline

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-04-22

First Submitted that Met QC Criteria
2010-06-29

First Posted (Estimated)
2010-06-30

Results Reporting Dates

Results First Submitted
2017-08-07

Results First Submitted that Met QC Criteria
2017-09-12

Results First Posted
2017-10-13

Study Record Updates

Last Update Submitted that met QC Criteria
2017-09-12

Last Update Posted
2017-10-13

Last Verified
2017-09

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

Patient level data for this study will be made available through www.clinicalstudydatarequest.com following the timelines and process described on this site.

Study Data/Documents

1. Dataset Specification (https://www.clinicalstudydatarequest.com)

   Information Identifier

   114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

2. Study Protocol (https://www.clinicalstudydatarequest.com)

Information Identifier

114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

3. Statistical Analysis Plan (https://www.clinicalstudydatarequest.com)

Information Identifier

114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

4. Clinical Study Report (https://www.clinicalstudydatarequest.com)

Information Identifier

114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

5. Informed Consent Form (https://www.clinicalstudydatarequest.com)

Information Identifier

114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

6. Individual Participant Data Set (https://www.clinicalstudydatarequest.com)

Information Identifier

114296

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by GlaxoSmithKline (Sirtris, a GSK Company)

Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research. (https://www.clinicalstudydatarequest.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Multiple-loading Dose Regimen Study in Patients With Chronic Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT00805480**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2015 02 10

Study Details Tab

Study Overview

Brief Summary

Loading dose, four arm, double blind, parallel group, placebo controlled study comparing single and multiple doses of AIN457 to placebo in patients with a diagnosis of moderate to severe chronic plaque psoriasis.

Feedback

Official Title

Phase II Randomized, Double blind, Multi center, Parallel group, Placebo controlled Multiple loading Dose Regimen Study to Assess the Safety, Efficacy and Duration of Response of AIN457 in Patients With Chronic Plaque type Psoriasis.

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: AIN457
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2212

Study Start

2008 12

Primary Completion (Actual)

2010 09

Study Completion (Actual)

2010 09

Enrollment (Actual)

130

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease

(https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Diagnosis of plaque psoriasis for at least 6 months prior to screening. The patients must meet all of the following criterion:
    1. Coverage of the body surface area (BSA) of 10% or more with plaques
    2. A score of 3 or more on the IGA scale
    3. A PASI score of at least 12 at baseline

Exclusion Criteria:

- Have forms of psoriasis other than the required "plaque psoriasis"
- Women of childbearing potential
- Recent use of investigational drugs or treatment with other biological therapies (wash out periods required)
- Previous treatment with this investigational drug
- Subjects with active or history of clinically significant cardiac, kidney or liver abnormalities;

Other protocol defined inclusion/exclusion criteria may apply

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 3 mg/kg Participants randomized to this arm received AIN457 3 mg/kg on day 1, and then matching placebo on days 15 and 29.	Drug: AIN457 • AIN457 was administered intravenously. • Other Names: ◦ Secukinumab Drug: Placebo • Matching placebo to AIN457 was administered intravenously.
Experimental: AIN457 10 mg/kg Participants randomized to this arm received AIN457 10 mg/kg on day 1, and then matching placebo on days 15 and 29.	Drug: AIN457 • AIN457 was administered intravenously. • Other Names: ◦ Secukinumab Drug: Placebo • Matching placebo to AIN457 was administered intravenously.
Experimental: AIN457 10 mg/kg x3 Participants randomized to this arm received AIN457 3 mg/kg on days 1, 15 and 29.	Drug: AIN457 • AIN457 was administered intravenously. • Other Names: ◦ Secukinumab
Placebo Comparator: Placebo Participants randomized to this arm	Drug: Placebo • Matching placebo to AIN457 was administered intravenously.

received matching placebo to AIN457 on days 1, 15 and 29	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Psoriasis Area and Severity Index (PASI) Scores	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	Baseline, Week 12
Percentage of Participants Who Had Not Relapsed at Any Time in the Trial	This outcome measure shows the proportion of participants in each of the AIN457 treatment groups who were relapse free throughout the study up to and including week 56.	Weeks 1, 2, 4, 6, 8, 10, 12, 14, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and 56

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentage of Participants With at Least 50% Improvement From Baseline in PASI	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, end of study (EOS) (up to week 56)
Percentage of Participants With at Least 75% or 90% Improvement From Baseline in PASI	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, EOS (up to week 56)
Percentage of Participants in Each Investigator Global Assessment (IGA) Category	The IGA scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe and 5 = very severe.	Weeks 1, 2, 4, 6, 8, 10, 12, 14, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, EOS (up

		to week 56)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals
- Principal Investigator: Novartis, Novartis Investigator Site

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2008-12-05

First Submitted that Met QC Criteria
2008-12-08

First Posted (Estimated)
2008-12-09

Results Reporting Dates

Results First Submitted
2015-01-28

Results First Submitted that Met QC Criteria
2015-01-28

Results First Posted (Estimated)
2015-02-10

Study Record Updates

Last Update Submitted that met QC Criteria
2015-01-28

Last Update Posted (Estimated)
2015-02-10

Last Verified
2015-01

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Plaque
psoriasis

inflammatory skin disease
skin condition, thickening
flaking
scaly patches
skin disease

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

Study terminated 26 June 2015 due to changes in the drug development portfolio. This study was not terminated for reasons of safety and/or efficacy

Study to Evaluate PF-04965842 in Patients With Moderate to Severe Psoriasis

ClinicalTrials.gov ID **NCT02201524**

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2016 10 05

Study Details Tab

Study Overview

Brief Summary

Feedback

Study B7451005 is a Phase 2 study which will assess the efficacy and safety of PF 04965842 in patients with moderate to severe psoriasis. The study will include three PF 04965842 groups (200 mg daily, 400 mg daily and 200 mg twice daily) and a placebo group. The treatment period will be 4 weeks in duration and will be followed up by a 4 week follow up period.

Official Title

A Phase 2, Randomized, Double blind, Placebo controlled Study To Evaluate Safety And Efficacy Of Pf 04965842 In Subjects With Moderate To Severe Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: PF 04965842
- Drug: PF 04965842
- Drug: PF 04965842
- Other: Placebo

Other Study ID Numbers

- B7451005
- JAK 1 FOR PSORIASIS (Other Identifier) (OTHER: Alias Study Number)

Study Start

2014 11

Primary Completion (Actual)

2015 09

Study Completion (Actual)

2015 09

Enrollment (Actual)

59

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 32505
Total Skin and Beauty Dermatology Center, PC

Arkansas Locations

Rogers, Arkansas, United States, 72758
Northwest Arkansas Clinical Trials Center, PLLC/Hull Dermatology, PA

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Have a diagnosis of plaque psoriasis for at least 6 months prior to first study dose.
2. Have plaque type psoriasis covering at least 15% of total BSA at Day 1 (at the time of the first study dose).
3. Have a PASI score of 12 or greater at Day 1 (at the time of the first study dose).
4. Be a candidate for phototherapy or systemic treatment of psoriasis (either naïve or history of previous treatment).

Exclusion Criteria:

1. Currently have non plaque forms of psoriasis, eg, erythrodermic, guttate, or pustular psoriasis.
2. 3. Have current drug induced psoriasis, eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, antimalarial drugs or lithium.
3. Have received any of the following treatment regimens specified in the timeframes outlined below:

Within 9 months of first dose of study drug:

• Ustekinumab (Stelara).

Within 12 weeks of first dose of study drug:

• Any experimental therapy for psoriasis or rheumatoid arthritis.

Within 4 8 weeks of first dose of study drug:

- Biologic therapies for psoriasis have discontinuation periods determined from approximately 5x half life of the respective biologic:
- 4 weeks: etanercept (Enbrel).
- 8 weeks: infliximab (Remicade), adalimumab (Humira).

Within 4 weeks of first dose of study drug:

- Systemic treatments other than biologics that could affect psoriasis (eg, oral or injectable corticosteroids, retinoids, methotrexate, cyclosporine, fumaric acid derivatives, sulfasalazine, hydroxycarbamide (hydroxyurea), azathioprine).
- Phototherapy and psoralen plus ultraviolet A therapy (PUVA).
- Other intramuscular gold, immunization with any live virus vaccination (eg, FluMist), herbal medications.

Within 2 weeks of first dose of study drug:

- Topical treatments that could affect psoriasis (eg, corticosteroids, tars, keratolytics, anthralin, vitamin D analogs, and retinoids).
- Phototherapy with ultraviolet B (UVB) (narrowband or broadband).

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Cohort 1 200mg of PF-04965842 twice daily	Drug: PF-04965842 • Subjects will receive 200 mg PF 04965842 twice daily for 4 weeks • Other Names: ◦ JAK1 inhibitor
Experimental: Cohort 2 400mg of PF-04965842 once daily	Drug: PF-04965842 • Subjects will receive 400 mg PF 04965842 daily for 4 weeks • Other Names: ◦ JAK1 inhibitor
Experimental: Cohort 3 200mg of PF-04965842 once daily	Drug: PF-04965842 • Subjects will receive 200 mg PF 04965842 daily for 4 weeks • Other Names: ◦ JAK1 inhibitor
Placebo Comparator: Cohort 4 Placebo comparator daily	Other: Placebo • Subjects will receive placebo for 4 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 4	PASI score is the combined assessment of lesion severity and area affected into single score range: 0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated: 0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il + Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4).	Baseline, Week 4

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in PASI Score at Week 1, 2, 3, 4, 5, 6, and 8	PASI score is the combined assessment of lesion severity and area affected into single score range: 0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated: 0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il +	Baseline, Week 1, 2, 3, 4, 5, 6, 8

	Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4).	
Change From Baseline in PASI Score at Week 1, 2, 3, 5, 6 and 8	PASI score is the combined assessment of lesion severity and area affected into single score range: 0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated: 0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il + Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4).	Baseline, Week 1, 2, 3, 5, 6, 8
Percentage of Participants Achieving 50 Percent Reduction From Baseline PASI Score at Week 1, 2, 3, 4, 5, 6, and 8	PASI score is combined assessment of lesion severity and area affected into single score range:0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated:0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il +	Baseline, Week 1, 2, 3, 4, 5, 6, 8

	Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4). Participants who had at least 50 percent reduction in PASI score relative to baseline PASI Score are reported. 90 percent confidence intervals are calculated using clopper-pearson (exact) method.	
Percentage of Participants Achieving 75 Percent Reduction From Baseline PASI Score at Week 1, 2, 3, 4, 5, 6 and 8	PASI score is combined assessment of lesion severity and area affected into single score range:0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated:0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il + Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4). Participants who had at least 75 percent reduction in PASI score relative to baseline PASI Score are reported. 90 percent confidence intervals are calculated using clopper-pearson (exact) method.	Baseline, Week 1, 2, 3, 4, 5, 6, 8
Percentage of Participants Achieving 90 Percent Reduction From Baseline PASI Score at	PASI score is combined assessment of lesion severity and area affected into single score range:0 (no disease) to 72 (maximal disease), with higher scores representing greater severity of psoriasis. Body divided into 4 sections (head and neck [h], arms [u], trunk [t], legs [l]); each area scored by itself	Baseline, Week 1, 2, 3, 4, 5, 6, 8 (early termination)

Week 1, 2, 3, 4, 5, 6, and 8	and scores combined for final PASI score. For each section, percent body surface area (A) of skin involved was estimated:0 (no involvement) to 6 (90-100 percent involvement), severity estimated by clinical signs: erythema (E), induration (I), scaling (S); 5 point scale: 0 (no involvement) to 4 (very marked involvement). Final PASI score = 0.1Ah (Eh + Ih + Sh) + 0.2Au (Eu + Iu + Su) + 0.3At (Et + It + St) + 0.4Al (El + Il + Sl), where head: 0.1; upper limbs: 0.2; trunk: 0.3; lower limbs: 0.4). Participants who had at least 90 percent reduction in PASI score relative to baseline PASI Score are reported. 90 percent confidence intervals are calculated using clopper-pearson (exact) method.	
Percentage of Participants Achieving Physician Global Assessment (PGA) Response of Clear or Almost Clear at Week 1, 2, 3, 4, 5, 6, and 8	The PGA of psoriasis was scored on a 5-point scale, reflecting a global consideration of the erythema (E), induration (I), and scaling (S) across all psoriatic lesions. The severity rating scores (erythema: 0= no evidence of erythema to 4= dark, deep red; Induration: 0= no evidence of plaque elevation to 4= marked plaque elevation, hard/sharp borders; Scaling: 0= no evidence of scaling to 4= thick, coarse scale predominates) were summed (E + I + S= total) and the average (total/3) was taken. The total average was rounded to the nearest whole number score to determine the PGA. The 5-point scale for PGA was: 0= clear; 1= almost clear; 2= mild; 3= moderate; 4= severe, where higher score indicating more severity. Participants with response of clear and almost clear were reported. 90 percent confidence intervals were calculated using clopper-pearson (exact) method.	Week 1, 2, 3, 4, 5, 6, 8

Change From Baseline in Fasting Lipids at Week 2, 4 and 8	Participants were required to fast 9 hours prior to sampling for lipid profile which included following parameters: low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C), cholesterol, triglycerides.	Baseline, Week 2, 4, 8 (early termination)
Change From Baseline in Lipid Ratios at Week 2, 4 and 8	The ratio of LDL-C/HDL-C was reported.	Baseline, Week 2, 4, 8 (early termination)
Change From Baseline in High Sensitivity C-Reactive Protein (hsCRP) at Week 1, 2, 3, 4, and 8	The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultrasensitive assay. Reference range for measurements is 0-0.5 mg/dL and lower limit of detection is less than (<) 0.015 mg/dL. Any value <0.015 mg/dL is imputed as 0.0075 mg/dL.	Baseline, Week 1, 2, 3, 4, 8 (early termination)
Number of Participants Reporting Clinically Significant Change From Baseline in Epstein-Barr Virus (EBV) Values	EBV samples were collected and changes from baseline were evaluated by the principal investigator (PI) for clinical significance. Clinical significance is levels outside of the normal range (abnormal levels) with clinically apparent viral disease, or that resulted in adverse event (AEs) or required follow-up.	Baseline up to Week 8 (early termination)
Number of Participants Reporting Clinically Significant Change From Baseline in	CMV samples were collected and changes from baseline were evaluated by the PI for clinical significance. Clinical significance is levels outside of the normal range (abnormal levels) with clinically apparent viral disease, or that resulted in AEs or required follow-up.	Baseline up to Week 8 (early termination)

Cytomegalovirus (CMV) Values		
Number of Participants Reporting Clinically Significant Change From Baseline in Herpes Simplex Virus Deoxyribonucleic Acid (HSV DNA) Values	HSV DNA samples were collected and changes from baseline were evaluated by the PI for clinical significance. Clinical significance is levels outside of the normal range (abnormal levels) with clinically apparent viral disease, or that resulted in AEs or required follow-up.	Baseline up to Week 8 (early termination)
Change From Baseline in Blood Pressure (BP) at Week 1, 2, 3, 4, 5, 6, and 8		Baseline, Week 1, 2, 3, 4, 5, 6, 8 (early termination)
Change From Baseline in Pulse Rate at Week 1, 2, 3, 4, 5, 6, and 8		Baseline, Week 1, 2, 3, 4, 5, 6, 8 (early termination)
Change From Baseline in Respiratory Rate at Week 1, 2, 3, 4, 5, 6, and 8		Baseline, Week 1, 2, 3, 4, 5, 6, 8 (early termination)
Change From Baseline in Body Temperature at Week 1, 2, 3, 4, 5, 6, and 8		Baseline, Week 1, 2, 3, 4, 5, 6, 8 (early termination)

Number of Participants Reporting Clinically Significant Change From Baseline in Heart Rate		Baseline up to Week 8 (early termination)
Number of Participants Reporting Clinically Significant Change From Baseline in Electrocardiogram (ECG) Parameters	ECG change data was reported as qualitative results, as per change in planned analysis. It was categorized as: normal; abnormal, not clinically significant or abnormal, clinically significant.	Baseline up to Week 8 (early termination)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2014-07-24

First Submitted that Met QC Criteria
2014-07-24

First Posted (Estimated)
2014-07-28

Results Reporting Dates

Results First Submitted
2016-08-11

Results First Submitted that Met QC Criteria
2016-08-11

Results First Posted (Estimated)
2016-10-05

Study Record Updates

Last Update Submitted that met QC Criteria
2016-08-11

Last Update Posted (Estimated)
2016-10-05

Last Verified

2016-08

More Information

Terms related to this study

Keywords Provided by Pfizer

Phase 2
randomized
double blind
placebo
plaque
psoriasis
safety
efficacy
JAK
janus kinase
moderate
severe

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Protein Kinase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Abrocitinib

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Pfizer

To obtain contact information for a study center near you, click here.
(https://trialinfoemail.pfizer.com/pages/landing.aspx?StudyID=B7451005&StudyName=Study%20to%20evaluate%20PF 04965842%20in%20Patients%20with%20Moderate%20to%20Severe%20Psoriasis)

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Record 1 of 1

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COMPLETED

Study to Evaluate Apo805K1 in Subjects With Moderate to Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID **NCT01483924**

Sponsor ApoPharma

Information provided by ApoPharma (Responsible Party)

Last Update Posted 2015 02 20

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of 12 weeks of treatment with Apo805K1 in subjects with moderate to severe chronic plaque psoriasis.

Feedback

Detailed Description

A) To evaluate the safety and tolerability of 12 weeks of treatment with Apo805K1

B) To evaluate the pharmacokinetics of Apo805K1 following daily administration for 14 days

C) To evaluate the efficacy and pharmacodynamics of Apo805K1

Official Title

A 12 week Randomized, Double blind, Placebo controlled, Multicenter, Multiple Sequential Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of Apo805K1 in Subjects With Moderate to Severe Chronic Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Apo805K1

Other Study ID Numbers

- AP03 0210

Study Start

2011 11

Primary Completion (Actual)

2013 08

Study Completion (Actual)

2013 10

Enrollment (Actual)

60

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Los Angeles, California, United States, 90017
Axis Clinical Trials

Los Angeles, California, United States, 90036
Axis Clinical Trials

Texas Locations



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Main Inclusion Criteria:

- A clinical diagnosis of moderate to severe chronic plaque psoriasis for at least 6 months (before Baseline assessment) with current body surface area (BSA) involvement ≥10% and Psoriasis Area Severity Index (PASI) ≥10.
- Male and female subjects 18 to 65 years of age, inclusive.
- At least one psoriatic plaque ≥6 mm in diameter (in a location suitable for biopsy).
- Signed and witnessed written informed consent form obtained prior to the first study intervention, as well as the ability to adhere to study restrictions, appointments and evaluation schedule.

Main Exclusion Criteria:

- Treatment of psoriasis with biologic agents within 90 days prior to Baseline assessment and during the study.
- Treatment with methotrexate, cyclosporine, retinoids, hydroxyurea or other systemic agents within 30 days prior to Baseline assessment and during the study.
- Phototherapy within 30 days prior to Baseline assessment and during the study.
- Psoriasis topical therapy within 14 days prior to Baseline assessment and during the study (exception: non medicated emollients and tar shampoo will be allowed).
- History of liver disease or abnormal liver enzymes
- Serum creatinine ≥1.5 times the upper limit of normal for age and sex matched controls.
- Previous treatment with Apo805K1or Thymodepressin or other immunosuppressant drugs.
- Evidence of skin conditions other than psoriasis (e.g., eczema) that could interfere with psoriasis assessments.
- History of chronic infection or malignancy

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 10 mg Apo805K1, or placebo	Drug: Apo805K1 • Sequential parallel dose escalation.
Experimental: 30 mg Apo805K1, or placebo	Drug: Apo805K1 • Sequential parallel dose escalation.
Experimental: 60 mg Apo805K1, or placebo	Drug: Apo805K1 • Sequential parallel dose escalation.
Experimental: 100 mg Apo805K1, or placebo	Drug: Apo805K1 • Sequential parallel dose escalation.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients With Adverse Events	The number of patients in each treatment group who reported at least 1 adverse event, including clinically significant changes from baseline in vital signs, 12-lead ECG, physical examinations and laboratory tests, from the time of the first dose until the last study visit.	12 Weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Cmax of Apo805K1 Following Multiple Doses, Assessed at Day 14	Cmax for dosages of 10 mg, 30 mg, 60 mg, or 100 mg Apo805K1, determined on Day 14. Serial blood samples for PK analysis were collected pre-dose and at 1, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose. .	12 hours
Tmax of Apo805K1 Following Multiple Doses, Assessed at Day 14	Tmax for dosages of 10 mg, 30 mg, 60 mg, or 100 mg Apo805K1, determined on Day 14. Serial blood samples for PK analysis were collected pre-dose and at 1, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose.	12 hours
AUC 0-infinity of Apo805K1 Following Multiple Doses, Assessed at Day 14	AUC 0-infinity for dosages of 10 mg, 30 mg, 60 mg, or 100 mg Apo805K1, determined on Day 14. Serial blood samples for PK analysis were collected pre-dose and at 1, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose.	12 hours

T 1/2 of Apo805K1 Following Multiple Doses, Assessed at Day 14	T 1/2 for dosages of 10 mg, 30 mg, 60 mg, or 100 mg Apo805K1, determined on Day 14. Serial blood samples for PK analysis were collected pre-dose and at 1, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose.	12 hours
Efficacy of Apo805K1 as Assessed by Change From Baseline in Psoriasis Area Severity Index (PASI) Scores	PASI is a quantitative measure of psoriasis that combines an assessment of the severity of lesions and a measurement of how much of the body surface area is affected into a single score ranging from 0 (no disease) to 72 (maximal disease). Thus, a decrease in PASI score indicates improvement. This outcome measure compared the difference in change in PASI score from baseline to Week 12 between the active treatment groups and the placebo group.	Baseline to 12 Weeks
Efficacy of APO805K1 as Assessed by Achievement of PASI-75	The proportion of patients in each treatment group who achieved at least a 75% improvement in PASI score from baseline at Week 12	12 weeks
Efficacy of Apo805K1 as Assessed by Change From Baseline at Week 12 in Lattice System-Physician Global Assessment (LS-PGA) Scores	The LS-PGA is a standardized method for determining categories of psoriasis severity. The percentage of body surface area involved is assessed on a scale ranging from 1 (0%) to 7 (51-100%); measures of plaque severity (thickness, erythema, and scaling) are assessed using a 4-point scale ranging from "none" to "marked"; and an algorithm is used to combine the above scores to determine a final score on a scale ranging from 0 (clear) to 7 (very severe). Thus, a decrease in LS-PGA score indicates improvement. This outcome measure compared the difference in change in LS-PGA score from baseline to Week 12 between the active treatment groups and the placebo group.	Baseline to 12 weeks

Efficacy of Apo805K1 as Assessed by Change From Baseline to Week 12 in Physician Global Assessment (PGA) Score	In the PGA, the physician assigns a single estimate of a patient s overall severity of the disease using a scale ranging from 0 (Clear) to 7 (Severe). (Unlike the LS-PGA, the individual elements of psoriasis plaque morphology or degree of body surface area involvement are not quantified.) Thus, a decrease in PGA score indicates improvement. This outcome measure compared the difference in change in PGA score from baseline to Week 12 between the active treatment groups and the placebo group.	Baseline to 12 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

ApoPharma

Collaborators

No information provided

Investigators

No information provided

Publications