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Completed **1**

A Study of Golimumab in Participants With Active Psoriatic Arthritis

ClinicalTrials.gov ID **NCT02181673**

Sponsor **Janssen Research & Development, LLC**

Information provided by **Janssen Research & Development, LLC (Responsible Party)**

Last Update Posted **2017-12-21**

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.
 - Data that is changed in the study record is color coded:
 - Deletions from the study record are shown crossed out in **red-highlights**.
 - Additions to the study record are shown in **green highlights**.

☐	1	2014-07-02	None (earliest version on record)
☐	2	2014-08-13	Study Status
☐	3	2014-09-24	Study Status
☐	4	2014-10-02	- Recruitment Status - Study Status - Contacts/Locations
☐	5	2014-10-23	- Study Status - Contacts/Locations
☐	6	2014-11-13	Study Status
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☐	12	2015-04-13	- Study Status - Contacts/Locations
☐	13	2015-05-04	- Study Status - Contacts/Locations
☐	14	2015-05-26	- Study Status - Contacts/Locations
☐	15	2015-06-29	- Study Status - Contacts/Locations
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			Compare

☐	17	2015-08-10	- Study Status - Contacts/Locations
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☐	19	2015-10-14	- Study Status - Contacts/Locations
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☐	23	2016-01-08	Study Status
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☐	26	2016-03-02	Study Status
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☐	28	2016-07-15	- Study Status - Conditions - Outcome Measures
☐	29	2016-10-05	Study Status
☐	30	2017-01-23	Study Status
☐	31	2017-02-23	Study Status
☐	32	2017-04-20	- Recruitment Status - Study Status - Oversight Results Submission Events (1) 2017-11-10: Returned after QC review: 2017-12-13
☐	33	2017-12-20	- Study Status - Outcome Measures - Participant Flow - Baseline Characteristics - Outcome Measures (Results) - Adverse Events - More Information

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Viewing V23 (2016-01-08)

Version

Date submitted
(YYYY-MM-DD)

Changes

Study Identification

Unique Protocol ID	CR103796
Brief Title	A Study of Golimumab in Participants With Active Psoriatic Arthritis
Official Title	A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNFα Monoclonal Antibody, Administered Intravenously, in Subjects With Active Psoriatic Arthritis
Secondary IDs	2014-000242-30, CNT0148PSA3001

Study Status

Record Verification	2016-01
Overall Status	Recruiting

Study Details

Study Start	2014-09
Primary Completion	2016-05 [Estimated]
Study Completion	2017-04 [Estimated]
First Submitted	2014-07-02
First Submitted that Met QC Criteria	2014-07-02
First Posted	2014-07-04 [Estimated]
Certification/Extension First Submitted	2017-01-23
Last Update Submitted that Met QC Criteria	2016-01-08
Last Update Posted	2016-01-11 [Estimated]

Sponsor/Collaborators

Sponsor	Janssen Research & Development, LLC
Responsible Party	Sponsor
Collaborators	

Version Date submitted
(YYYY-MM-DD) Changes

oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	Yes

Study Description

Brief Summary	The purpose of this study is to evaluate the efficacy of intravenously (administration of a fluid into the vein) administered golimumab 2 milligram per kilogram (mg/kg) in participants with active psoriatic arthritis (a chronic inflammatory arthritis that is associated with psoriasis).
Detailed Description	This is a Phase 3, multicenter (when more than one hospital or medical school team work on a medical research study), randomized (study drug assigned by chance), double-blind (neither the researchers nor the participants know what treatment the participant is receiving), placebo-controlled (an inactive substance; a pretend treatment [with no drug in it] that is compared in a clinical trial with a drug to test if the drug has a real effect) study of golimumab compared with placebo in participants with active psoriatic arthritis. The study will include 4 phases: Screening phase (up to 6 weeks), Double-blind placebo-controlled phase (Week 0 to Week 24), Active treatment phase (Week 24 to Week 52), and Safety follow-up phase (8 weeks from last study drug administration). Total duration of the study will be 60 weeks per participant. Eligible Participants will be randomly assigned to either Treatment Group 1: Placebo or Treatment Group 2: Golimumab. Participants randomized to Placebo Group, will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20. At Week 24, all participants receiving placebo will begin receiving intravenous infusions of golimumab (2 mg/kg) at Week 24, 28 and thereafter every 8 weeks up to Week 52. Participants randomized to Golimumab Group, will receive intravenous infusions of golimumab 2 mg/kg at Week 0, 4 and thereafter every 8 weeks up to Week 52. At Week 24, participants randomized to golimumab Group will receive a placebo infusion to maintain the blind. The efficacy will be assessed primarily by measuring percentage of participants who achieve a 20 percent improvement from baseline in the assessment used in active psoriatic arthritis at Week 14. Participants' safety will be monitored throughout the study.

Conditions

Condition	Psoriatic Arthritis
Keywords	Psoriatic arthritis Golimumab Simponi

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 3
Interventional Study Model	Parallel Assignment
Number of Arms	2
Masking	Double (Participant, Investigator)
Allocation	Randomized
Enrollment	440 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Treatment Group 1: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20. At Week 24, all participants receiving placebo will begin receiving intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and thereafter every 8 weeks up to Week 52.	Drug: Placebo - Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20 in treatment Group 1 and intravenous infusions of placebo at Week 24 to maintain the blind in treatment Group 2. Drug: Golimumab - Participants will receive intravenous infusions of golimumab 2mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52 in treatment Group 2 and intravenous infusions of golimumab (2mg/kg) at Weeks 24, 28 and thereafter every 8 weeks up to Week 52 in treatment Group 1.
Experimental: Treatment Group 2: Golimumab Participants will receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52. At Week 24, participants will receive a placebo infusion to maintain the blind.	Drug: Placebo - Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20 in treatment Group 1 and intravenous infusions of placebo at Week 24 to maintain the blind in treatment Group 2. Drug: Golimumab - Participants will receive intravenous infusions of golimumab 2mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52 in treatment Group 2 and intravenous infusions of golimumab (2mg/kg) at Weeks 24, 28 and thereafter every 8 weeks up to Week 52 in treatment Group 1.

Outcome Measures

Primary Outcome Measures	Percentage of Participants who Achieve an American College of Rheumatology (ACR) 20 Response at Week 14 The ACR 20 response is defined as greater or equal to ($\geq$) 20 percent (%) improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and $\geq$20% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 centimeter [cm] scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). [Time Frame: Week 14]
Secondary Outcome Measures	- Change from baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) score at Week 14 The HAQ-DI assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living), each scored from 0 (no difficulty) to 3 (inability to perform a task). [Time Frame: Baseline and week 14] - Percentage of Participants who Achieve an ACR 50 Response at Week 14 The ACR 50 response is defined as: greater or equal to ($\geq$) 50 percent (%) improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and $\geq$50% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 cm scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). [Time Frame: Week 14] - Percentage of Participants achieving Psoriatic Area and Severity Index (PASI) 75 response at Week 14 The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy that is scored from 0 to 72. PASI 75 response is defined as $\geq$75% improvement in PASI score from baseline. [Time Frame: Week 14] - Change from baseline in total modified van der Heijde-Sharp (vdH-S) score at Week 24 The vdH-S score is the sum of joint erosion score and joint-space narrowing (JSN) score based on x-rays of both hands and both feet. The total score ranges from 0 to 528 with higher scores indicating more joint damage. For the change from baseline, positive values show an increase in damage. [Time Frame: Baseline and Week 24] - Change from baseline in 36-item short form health survey (SF-36) physical Component Summary (PCS) at Week 14 36-Item Short-Form Health Survey (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 can also be summarized as physical and mental component scores. All scores are based on a scale from 0 to 100, with higher scores indicating more favorable health state. [Time Frame: Baseline and week 14]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: - Have had psoriatic arthritis (PsA) for at least 6 months prior to the first administration of study agent - Have a diagnosis of active PSA as defined by 5 or more swollen joints and 5 or more tender joints at Screening and at Baseline and C-reactive protein ≥ 0.6 milligram per deciliter (mg/dL) at Screening - Have active plaque psoriasis or a documented history of plaque psoriasis - Have active PsA despite current or previous disease-modifying antirheumatic drugs (DMARD) and/or nonsteroidal anti-inflammatory drug (NSAID) therapy. DMARD therapy is defined as taking a DMARD for at least 3 months, or evidence of DMARD intolerance. NSAID therapy is defined as taking an NSAID for at least 4 weeks or evidence of NSAID intolerance Exclusion Criteria: - Have other inflammatory diseases that might confound the evaluations of benefit of Golimumab therapy, including but not limited to rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus, or Lyme disease - Are pregnant, nursing, or planning a pregnancy or fathering a child while enrolled in the study or within 4 months after receiving the last administration of study agent - Have used any biologic agents that are targeted for reducing tumor necrosis factors (TNF) alpha, including but not limited to Infliximab, Etanercept, Adalimumab, Golimumab, and Certolizumab Pegol - Have ever used cytotoxic drugs, including Chlorambucil, Cyclophosphamide, Nitrogen mustard, or other Alkylating agents

Contacts/Locations

Central Contact Person	- Name: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions: - Email: JNJ.CT@sylogent.com
Study Officials	- Name: Janssen Research & Development, LLC Clinical Trial - Role: Study Director - Affiliation: Janssen Research & Development, LLC
Location	Birmingham, Alabama, United States Status: Withdrawn Glendale, Arizona, United States Status: Recruiting Glendale, Arizona, United States Status: Withdrawn Mesa, Arizona, United States Status: Recruiting Huntington Beach, California, United States Status: Completed La Jolla, California, United States Status: Withdrawn Lakewood, California, United States Status: Recruiting Farmington, Connecticut, United States Status: Withdrawn Chicago, Illinois, United States Status: Withdrawn Granger, Indiana, United States Status: Recruiting Indianapolis, Indiana, United States Status: Completed Monroe, Louisiana, United States Status: Withdrawn Monroe, Louisiana, United States Status: Recruiting Wheaton, Maryland, United States Status: Withdrawn Lansing, Michigan, United States Status: Withdrawn Tupelo, Mississippi, United States Status: Completed

- **St Louis, Missouri, United States**
Status: **Withdrawn**
- **St Louis, Missouri, United States**
Status: **Recruiting**
- **Nashville, Nevada, United States**
Status: **Withdrawn**
- **Clifton, New Jersey, United States**
Status: **Withdrawn**
- **Freehold, New Jersey, United States**
Status: **Withdrawn**
- **Midland Park, New Jersey, United States**
Status: **Withdrawn**
- **New York, New York, United States**
Status: **Withdrawn**
- **Orchard Park, New York, United States**
Status: **Completed**
- **Hickory, North Carolina, United States**
Status: **Withdrawn**
- **Raleigh, North Carolina, United States**
Status: **Withdrawn**
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Status: **Recruiting**
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Status: **Withdrawn**
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Status: **Recruiting**
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Status: **Recruiting**
- **Houston, Texas, United States**
Status: **Withdrawn**
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Status: **Withdrawn**
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- **Kogarah, Australia**
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- **Maroochydore, Australia**
Status: **Recruiting**
- **Southport, Australia**
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- **Victoria Park, Australia**
Status: **Withdrawn**
- **Grodno, Belarus**
Status: **Recruiting**
- **Homyl, Belarus**
Status: **Withdrawn**
- **Homyl, Belarus**
Status: **Recruiting**
- **Minsk, Belarus**
Status: **Recruiting**
- **Vitebsk, Belarus**
Status: **Recruiting**
- **Vychulki, Brest Region, Brest, Belarus**
Status: **Withdrawn**
- **St. John's, Newfoundland and Labrador, Canada**
Status: **Recruiting**
- **Barrie, Ontario, Canada**
Status: **Withdrawn**
- **St. Catharines, Ontario, Canada**
Status: **Withdrawn**
- **Waterloo, Ontario, Canada**
Status: **Completed**
- **Québec, Quebec, Canada**
Status: **Withdrawn**
- **Saskatoon, Saskatchewan, Canada**
Status: **Withdrawn**
- **Burlington, Canada**
Status: **Completed**
- **Bad Doberan, Germany**
Status: **Completed**

• Berlin, Germany	
Status:	Recruiting
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Status:	Recruiting
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Status:	Completed
• Hamburg, Germany	
Status:	Recruiting
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Status:	Withdrawn
• Osnabrück, Germany	
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• Planegg, Germany	
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• Plauen, Germany	
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• Ratingen, Germany	
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• Tübingen, Germany	
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• Kaunas, Lithuania	
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Status:	Recruiting

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Status:	Recruiting
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• Ploiești, Romania	
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• Sibiu, Romania	
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Status:	Recruiting
• Korolyov, Russia	
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• Krasnoyarsk, Russia	
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• Moscow, Russia	
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Status:	Withdrawn

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