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A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI)

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2016 by Janssen Research & Development, LLC

Sponsor:
Janssen Research & Development, LLC

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

ClinicalTrials.gov Identifier:
NCT02407236

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History of Changes

- Full Text View • Tabular View • No Study Results Posted • Disclaimer • How to Read a Study Record

Purpose

The purpose of this study is to evaluate the efficacy and safety of ustekinumab as intravenous (IV: into the vein) infusion in induction study in participants with moderately to severely active Ulcerative Colitis (UC) and as subcutaneous (SC) administration in maintenance study in participants with moderately to severely active Ulcerative Colitis (UC) who have demonstrated a clinical response to Induction treatment with IV ustekinumab.

Condition	Intervention	Phase
Colitis, Ulcerative Inflammatory Bowel Diseases	Drug: Placebo IV Drug: Placebo SC Drug: Ustekinumab IV Drug: Ustekinumab SC	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)

Official Title: A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis

Resource links provided by NLM:

Genetics Home Reference related topics: ulcerative colitis

MedlinePlus related topics: Ulcerative Colitis

Drug Information available for: Ustekinumab

U.S. FDA Resources

Further study details as provided by Janssen Research & Development, LLC:

Primary Outcome Measures:

- Induction Study - Number of Participants With Clinical Remission [Time Frame: Week 8] [Designated as safety issue: No]

  The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore greater than (>) 1, for countries outside the United States (US). For the US, Clinical remission is defined as absolute stool number <=3, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity for ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, findings on flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating more severe disease activity.

- Maintenance Study - Number of Participants with Clinical Remission Among Participants in Clinical Response to IV Ustekinumab Induction Treatment [Time Frame: Week 44] [Designated as safety issue: No]

  The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore greater than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity for ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, findings on flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating more severe disease activity.

Secondary Outcome Measures:

- Induction Study - Number of Participants with Clinical Response [Time Frame: Week 8] [Designated as safety issue: No]

  Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to (>=) 30 percent (%) and >=3 points, with either a decrease from induction baseline in the rectal bleeding subscore >=1 or rectal bleeding subscore = 0 or 1.

- Induction Study - Number of Participants With Endoscopic Healing [Time Frame: Week 8] [Designated as safety issue: No]

  Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore = 0 or 1.

- Induction Study - Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Score [Time Frame: Week 8] [Designated as safety issue: No]

  The IBDQ is a 32-item questionnaire for participants with Inflammatory Bowel Disease (IBD) that will be used to evaluate the disease-specific health-related quality of life across 4 dimensional scores: bowel (loose stools, abdominal pain), systemic (fatigue, altered sleep pattern), social (work attendance, need to cancel social events), and emotional (anger, depression, irritability). The total score ranges from 32 to 224 with higher scores indicating better quality of life.

- Maintenance Study - Number of Participants with Clinical Response Among Participants in Clinical Response to IV Ustekinumab Induction Treatment [Time Frame: Through Week 44] [Designated as safety issue: No]

  Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to (>=) 30 percent (%) and >=3 points, with either a decrease from Induction baseline in the rectal bleeding subscore >=1 or rectal bleeding subscore = 0 or 1.

- Maintenance Study - Number of Participants with Endoscopic Healing Among Participants in Clinical Response to IV Ustekinumab Induction Treatment [Time Frame: Week 44] [Designated as safety issue: No]

  Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore = 0 or 1.

- Maintenance Study - Number of Participants with Clinical Remission Among those who Achieved Clinical Remission at Maintenance Study Baseline [Time Frame: Through Week 44] [Designated as safety issue: No]

  The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore greater than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity for ulcerative colitis.

- Maintenance Study - Number of Participants with Clinical Remission and not Receiving Concomitant Corticosteroids Among those Receiving Concomitant Corticosteroids at Maintenance Baseline [Time Frame: Week 44] [Designated as safety issue: No]

  The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore greater than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity for ulcerative colitis.

Estimated Enrollment:	951
Study Start Date:	July 2015
Estimated Study Completion Date:	July 2021
Estimated Primary Completion Date:	April 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Induction Study - Placebo Intravenous (IV) Participants will be randomized to receive single dose of placebo as Intravenous (IV: into the vein) infusion at Week 0. Participants with clinical response at Week 8 will be eligible	Drug: Placebo IV Placebo will be administered as intravenous infusion.

to enter the Maintenance study, but will not be randomized.	
Experimental: Induction Study - Ustekinumab 130 milligram (mg) IV Participants will be randomized to receive single dose of ustekinumab 130 mg as IV infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion at Week 0 or Week 8 in Induction Study.
Experimental: Induction Study - Ustekinumab 6 mg/kg IV Participants will be randomized to receive ustekinumab approximating 6 mg/kg of body weight, as intravenous infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion at Week 0 or Week 8 in Induction Study.
Induction Study- Placebo- Nonresponsders at Week 8 Participants without clinical response to placebo at Week 8 will receive a single IV infusion of ustekinumab approximating 6mg/kg along with matching subcutaneous (SC) placebo (to maintain the blind). Participants in clinical response at Week 16 will be eligible to enter Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion at Week 0 or Week 8 in Induction Study.
Induction study-Ustekinumab Nonresponders at Week 8 Participants without clinical response to ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 will receive a single dose of ustekinumab 90 mg subcutaneously along with matching placebo intravenously (to maintain the blind). Participants in clinical response at Week 16 (that is, delayed responders) will be eligible to enter Maintenance study, but will not be randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Placebo Comparator: Maintenance Study - Placebo Subcutaneous (SC) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 12 weeks Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 12 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 8 weeks (q8w) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Maintenance Study - Placebo IV - Responder - Placebo SC Participants in clinical response to Induction treatment with IV Placebo will receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Maintenance Study-Delayed Responder-Ustekinumab 90mg SC q8w Participants without clinical response to induction treatment ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 but in clinical response at Week 16 after receiving Induction Ustekinumab at week 8 (delayed responders) will receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.

Detailed Description:

This is a Phase 3, randomized (assignment of study drug by chance), double-blind (neither the participant or study staff will know the identity of study drugs), placebo-controlled (placebo is an inactive substance that is compared with a drug to test whether the drug has a real effect in a clinical trial), parallel-group (a medical research study comparing the response in 2 or more groups of participants receiving different interventions), multi-center (more than one clinical site will work on a medical research study), protocol of ustekinumab. The protocol will consist of 2 studies: an Induction study and a Maintenance study with unique endpoints. Screening period will be up to 8 Weeks. Induction study will be at least 8 weeks duration for each participant. Participant with clinical response in the Induction study will be eligible for the Maintenance study. The Maintenance study will be 44 weeks duration. After completion of the maintenance study, a long term extension will follow eligible participants for an additional 3 years. Clinical remission will be evaluated at Week 8 in the Induction study. Clinical remission among ustekinumab Induction responders will be evaluated at week 44 in the Maintenance study. Participants' safety will be monitored throughout.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Has a clinical diagnosis of Ulcerative Colitis (UC) at least 3 months before Screening
- Has moderately to severely active UC, defined as a Baseline (Week 0) Mayo score of 6 to 12, including a Screening endoscopy subscore of the Mayo score greater than or equal to (>=) 2 as determined by a central reading of the video endoscopy
- Have failed biologic therapy, that is, have received treatment with 1 or more tumour necrosis factor (TNF) antagonists or vedolizumab at a dose approved for the treatment of UC, and have a documented history of failure to respond to or tolerate such treatment; OR Be naïve to biologic therapy (TNF antagonists or vedolizumab) or have received biologic therapy but have not demonstrated a history of failure to respond to, or tolerate, a biologic therapy and have a prior or current UC medication history that includes at least 1 of the following: a. Inadequate response to or failure to tolerate current treatment with oral corticosteroids or immunomodulators (6-mercaptopurine [6-MP] or azathioprine [AZA]) OR b. History of failure to respond to, or tolerate, at least 1 of the following therapies: oral or IV corticosteroids or immunomodulators (6-MP or AZA) OR c. History of corticosteroid dependence (that is, an inability to successfully taper corticosteroids without a return of the symptoms of UC)
- Before the first administration of study agent, the following conditions must be met: vedolizumab must have been discontinued for at least 4 months and anti-tumor necrosis factors (TNFs) for at least 8 weeks

Exclusion Criteria:

- Has severe extensive colitis and is at imminent risk of colectomy
- Has UC limited to the rectum only or to < 20 centimeters (cm) of the colon
- Presence of a stoma or history of a fistula
- Participants with history of extensive colonic resection (for example, less than 30 cm of colon remaining) that would prevent adequate evaluation of the effect of study agent on clinical disease activity
- Participants with history of colonic mucosal dysplasia. Participants will not be excluded from the study because of a pathology finding of "indefinite dysplasia with reactive atypia"

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02407236

Contacts

Contact: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions: JNJ.CT@sylogent.com

Show 301 Study Locations

Sponsors and Collaborators

Janssen Research & Development, LLC

Investigators

Study Director: Janssen Research & Development, LLC Clinical Trial Janssen Research & Development, LLC

More Information

Additional Information:

To learn how to participate in this trial please click here.

Responsible Party:	Janssen Research & Development, LLC
ClinicalTrials.gov Identifier:	NCT02407236 History of Changes
Other Study ID Numbers:	CR106920 2014-005606-38 CNTO1275UCO3001
Study First Received:	March 30, 2015
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Health Authority:	United States: Food and Drug Administration Canada: Health Canada Israel: Israeli Health Ministry Pharmaceutical Administration Russia: Ministry of Health of the Russian Federation Serbia: Medicines and Medical Devices Agency South Africa: Medicines Control Council Australia: Department of Health and Ageing Therapeutic Goods Administration South Korea: Ministry of Food and Drug Safety New Zealand: New Zealand Medicines and Medical Devices Safety Authority United Kingdom: Medicines and Healthcare Products Regulatory Agency Poland: Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczychul Hungary: National Institute of Pharmacy Germany: Paul-Ehrlich-Institut

France: Agence Nationale de Sécurité du Médicament et des produits de santé
Denmark: Danish Health and Medicines Authority
Bulgaria: Bulgarian Drug Agency
Austria: Bundesamt für Sicherheit im Gesundheitswesen
Belgium: Agence Fédérale des Médicaments et Produits de Santé
Czech Republic: Statni Ustav pro kontrolu leciv
Italy: Agenzia Italiana del Farmaco
Netherlands: Centrale Commissie Mensgebonden Onderzoek
Romania: Agentia Nationala a Medicamentului si a Dispozitivelor Medicale
Slovak Republic: Štátny ústav pre kontrolu liečiv

Keywords provided by Janssen Research & Development, LLC:
Ustekinumab
Inflammatory Bowel Diseases (IBD)
Colitis, Ulcerative

Additional relevant MeSH terms:
Ulcer
Colitis, Ulcerative
Colitis
Intestinal Diseases
Inflammatory Bowel Diseases
Pathologic Processes
Gastroenteritis
Gastrointestinal Diseases
Digestive System Diseases
Colonic Diseases
Ustekinumab
Dermatologic Agents

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