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Study of Vedolizumab (MLN0002) in Patients With Moderate to Severe Ulcerative Colitis (GEMINI I)

This study has been completed.

Sponsor:

Millennium Pharmaceuticals, Inc.

Information provided by (Responsible Party):

Millennium Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:

NCT00783718

First received: October 31, 2008

Last updated: June 19, 2014

Last verified: June 2014

[History of Changes](#)

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► Purpose

The primary purpose of this study was to determine the effect of vedolizumab induction treatment on clinical response at 6 weeks and to determine the effect of vedolizumab maintenance treatment on clinical remission at 52 weeks.

Condition	Intervention	Phase
Ulcerative Colitis	Drug: vedolizumab Other: Placebo	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Triple (Participant, Care Provider, Investigator)

Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients With Moderate to Severe Ulcerative Colitis

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [ulcerative colitis](#)

[MedlinePlus](#) related topics: [Ulcerative Colitis](#)

[Drug Information](#) available for: [Vedolizumab](#)

[U.S. FDA Resources](#)

Further study details as provided by Millennium Pharmaceuticals, Inc.:

Primary Outcome Measures:

- Induction Phase: Percentage of Participants With a Clinical Response at Week 6 [Time Frame: Baseline and Week 6]

Clinical response is defined as a reduction in complete Mayo score of ≥ 3 points and $\geq 30\%$ from Baseline with an accompanying decrease in rectal bleeding subscore of ≥ 1 point or absolute rectal bleeding subscore of ≤ 1 point.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving clinical response.

- Maintenance Phase: Percentage of Participants in Clinical Remission at Week 52 [Time Frame: Week 52]

Clinical Remission is defined as a complete Mayo score of ≤ 2 points and no individual subscore > 1 point.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving clinical remission.

Secondary Outcome Measures:

- Induction Phase: Percentage of Participants in Clinical Remission at Week 6 [Time Frame: Week 6]

Clinical Remission is defined as a complete Mayo score of ≤ 2 points and no individual subscore > 1 point.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving clinical remission.

- Induction Phase: Percentage of Participants With Mucosal Healing at Week 6 [Time Frame: Week 6]

Mucosal healing is defined as a Mayo endoscopic subscore of ≤ 1 point.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Endoscopic findings were scored on a scale from 0 to 3 as follows:

0 = Normal or inactive disease; 1 = Mild disease (erythema, decreased vascular pattern, mild friability); 2 = Moderate disease (marked erythema, lack of vascular pattern, friability, erosions); 3 = Severe disease (spontaneous bleeding, ulceration).

All participants who prematurely discontinued for any reason were considered as not achieving mucosal healing.

- Maintenance Phase: Percentage of Participants With Durable Clinical Response [Time Frame: Baseline, Week 6 and Week 52]

Durable clinical response is defined as reduction in complete Mayo score of ≥ 3 points and $\geq 30\%$ from Baseline (Week 0) with an accompanying decrease in rectal bleeding subscore of ≥ 1 point or absolute rectal bleeding subscore of ≤ 1 point at both Weeks 6 and 52. The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving durable clinical response.

- Maintenance Phase: Percentage of Participants With Mucosal Healing at Week 52 [Time Frame: Week 52]

Mucosal healing is defined as a Mayo endoscopic subscore of ≤ 1 point.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Endoscopic findings were scored on a scale from 0 to 3 as follows:

0 = Normal or inactive disease; 1 = Mild disease (erythema, decreased vascular pattern, mild friability); 2 = Moderate disease (marked erythema, lack of vascular pattern, friability, erosions); 3 = Severe disease (spontaneous bleeding, ulceration).

All participants who prematurely discontinued for any reason were considered as not achieving mucosal healing.

- Maintenance Phase: Percentage of Participants With Durable Clinical Remission [Time Frame: Week 6 and Week 52]

Durable clinical remission is defined as complete Mayo score of ≤ 2 points and no individual subscore > 1 point at both Weeks 6 and 52. The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving durable clinical remission.

- Maintenance Phase: Percentage of Participants With Corticosteroid-free Remission at Week 52
[Time Frame: Week 52]

Clinical Remission is defined as a complete Mayo score of ≤ 2 points and no individual subscore > 1 point. Corticosteroid-free clinical remission is defined as participants using oral corticosteroids at baseline (Week 0) who discontinued corticosteroids and were in clinical remission at Week 52.

The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

All participants who prematurely discontinued for any reason were considered as not achieving corticosteroid-free remission.

Enrollment: 895
Study Start Date: January 2009
Study Completion Date: March 2012
Primary Completion Date: December 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Vedolizumab In the Induction Phase participants received vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2 (Days 1 and 15). In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria were randomized in a 1:1:1 ratio to double-blind treatment with vedolizumab administered every 4 weeks, vedolizumab administered every 8 weeks, or placebo for up to Week 50. Participants who did not demonstrate response at Week 6 of the Induction Phase continued treatment with vedolizumab, administered every 4 weeks during the Maintenance Phase.	Drug: vedolizumab Vedolizumab for intravenous infusion Other Names: • Entyvio • MLN0002 • MLN02 • LDP-02
Placebo Comparator: Placebo In the Induction Phase participants received placebo intravenous infusion at Week 0 and Week 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction.	Other: Placebo Placebo intravenous infusion

Detailed Description:

This multicenter, phase 3, randomized, blinded, placebo-controlled study in patients with moderately to severely active ulcerative colitis comprises two phases:

- The Induction Phase, designed to establish the efficacy and safety of vedolizumab for the induction of clinical response and remission.

- The Maintenance Phase, designed to establish the efficacy and safety of vedolizumab for the maintenance of clinical response and remission.

The 6-week Induction Phase contained 2 cohorts of participants: Cohort 1 participants were randomized and treated with double-blind study drug, and Cohort 2 participants were treated with open-label vedolizumab. The second cohort was enrolled to ensure that the sample size of Induction Phase responders randomized into the Maintenance Study provided sufficient power for the Maintenance Study primary efficacy analysis. These participants did not contribute to the efficacy analyses performed for the Induction Study. Participants in both cohorts were assessed for treatment response at Week 6.

In the Maintenance Phase vedolizumab-treated participants from both Cohort 1 and Cohort 2 who demonstrated a clinical response were randomized in a 1:1:1 ratio to double-blind treatment with vedolizumab administered every 4 weeks (Q4W), vedolizumab administered every 8 weeks (Q8W), or placebo. Vedolizumab-treated participants who did not demonstrate response at Week 6 continued treatment with open-label vedolizumab, administered Q4W. Participants treated with double-blind placebo in the Induction Phase continued on double-blind placebo during the Maintenance Phase, regardless of treatment response during induction. The Maintenance Phase began at Week 6 and concluded with Week 52 assessments.

After the Week 52 assessments, participants meeting protocol-defined criteria were eligible to enroll in Study C13008 (NCT00790933; Long-term Safety) to receive open-label vedolizumab treatment. Participants who withdrew early (prior to Week 52) due to sustained nonresponse, disease worsening, or the need for rescue medications may also have been eligible for Study C13008. Participants who did not enroll into Study C13008 were to complete a final on-study safety assessment at Week 66 (or final safety visit 16 weeks after the last dose) in the Maintenance Phase of Study C13006.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Each patient must meet all of the following inclusion criteria to be enrolled in the study:

1. Diagnosis of moderately to severely active ulcerative colitis
2. Demonstrated, over the previous 5 year period, an inadequate response to, loss of response to, or intolerance at least 1 of the following agents:
 1. Immunomodulators
 2. Tumor necrosis factor-alpha (TNF α) antagonists
 3. Corticosteroids
3. May be receiving a therapeutic dose of conventional therapies for inflammatory bowel disease (IBD) as defined by the protocol

Exclusion Criteria:

1. Evidence of abdominal abscess at the initial screening visit
2. Extensive colonic resection, subtotal or total colectomy
3. Ileostomy, colostomy, or known fixed symptomatic stenosis of the intestine

4. Have received non permitted IBD therapies within either 30 or 60 days, depending on the medication, as stated in the protocol
5. Chronic hepatitis B or C infection
6. Active or latent tuberculosis

▶ 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: NCT00783718

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Sponsors and Collaborators

Millennium Pharmaceuticals, Inc.

Investigators

Study Director: Medical Monitor Millennium Pharmaceuticals, Inc.

▶ More Information

Publications:

[Feagan BG, Rutgeerts P, Sands BE, Hanauer S, Colombel JF, Sandborn WJ, Van Assche G, Axler J, Kim HJ, Danese S, Fox I, Milch C, Sankoh S, Wyant T, Xu J, Parikh A; GEMINI 1 Study Group. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2013 Aug 22;369\(8\):699-710. doi: 10.1056/NEJMoa1215734.](#)

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

[Arijs I, De Hertogh G, Lemmens B, Van Lommel L, de Bruyn M, Vanhove W, Cleynen I, Machiels K, Ferrante M, Schuit F, Van Assche G, Rutgeerts P, Vermeire S. Effect of vedolizumab \(anti- \$\alpha 4\beta 7\$ -integrin\) therapy on histological healing and mucosal gene expression in patients with UC. Gut. 2016 Oct 7. pii: gutjnl-2016-312293. doi: 10.1136/gutjnl-2016-312293. \[Epub ahead of print\]](#)

[Feagan BG, Rubin DT, Danese S, Vermeire S, Abhyankar B, Sankoh S, James A, Smyth M. Efficacy of Vedolizumab Induction and Maintenance Therapy in Patients With Ulcerative Colitis, Regardless of Prior Exposure to Tumor Necrosis Factor Antagonists. Clin Gastroenterol Hepatol. 2017 Feb;15\(2\):229-239.e5. doi: 10.1016/j.cgh.2016.08.044. Epub 2016 Sep 14.](#)

[Rosario M, Dirks NL, Gastonguay MR, Fasanmade AA, Wyant T, Parikh A, Sandborn WJ, Feagan BG, Reinisch W, Fox I. Population pharmacokinetics-pharmacodynamics of vedolizumab in patients with ulcerative colitis and Crohn's disease. Aliment Pharmacol Ther. 2015 Jul;42\(2\):188-202. doi: 10.1111/apt.13243. Epub 2015 May 20. Erratum in: Aliment Pharmacol Ther. 2015 Nov;42\(9\):1135.](#)

Responsible Party: Millennium Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier: [NCT00783718](#) [History of Changes](#)

Other Study ID Numbers: C13006
U1111-1156-8422 (Registry Identifier: WHO)
2008-002782-32 (EudraCT Number)
NL25207.096.08 (Registry Identifier: CCMO)
CTRI/2009/091/000128 (Registry Identifier: CTRI)
NMRR-08-1046-2201 (Registry Identifier: NMRR)
C13006CTIL (Other Identifier: Israel MoH)
09/H1102/66 (Registry Identifier: NRES)

Study First Received: October 31, 2008

Results First Received: June 19, 2014

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Additional relevant MeSH terms:

Colitis	Colonic Diseases
Ulcer	Intestinal Diseases
Colitis, Ulcerative	Pathologic Processes
Gastroenteritis	Inflammatory Bowel Diseases
Gastrointestinal Diseases	Vedolizumab
Digestive System Diseases	Gastrointestinal Agents

ClinicalTrials.gov processed this record on August 29, 2017