

Ulcerative Colitis

**A Study of the Efficacy and Safety of Etrolizumab Treatment
in Maintenance of Disease Remission in Ulcerative Colitis (UC)
Participants Who Are Naive to Tumor Necrosis Factor (TNF)
Inhibitors**

Trial Status
Completed

Trial Runs In
15 Countries

Trial Identifier
NCT02165215 2013-004280-31
GA29102

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy (Maintenance of Remission) and Safety of Etrolizumab Compared With Placebo in Patients With Moderate to Severe Active Ulcerative Colitis Who Are Naive to TNF Inhibitors

Trial Summary:

This Phase III, randomized, double-blind, parallel-grouped, placebo-controlled, multicenter study will investigate the efficacy and safety of etrolizumab in maintenance of remission in participants with moderately to severely active UC who are naive to TNF inhibitors and refractory to or intolerant of prior immunosuppressant and/or corticosteroid treatment.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02165215 2013-004280-31 GA29102
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
18 Years & # 80 Years

Healthy Volunteers
No

Inclusion Criteria:

ForPatients

by Roche

- Diagnosis of ulcerative colitis (UC) established at least 3 months prior to Day 1 by clinical and endoscopic evidence
- Moderately to severely active UC as determined by an MCS of 6-12 with an endoscopic subscore greater than or equal to (#)2 as determined by the central reading procedure (endoscopy to be performed 4-16 days prior to Day 1), a rectal bleeding subscore #1, and a stool frequency subscore #1 during the screening period (prior to Day 1)
- Evidence of UC extending a minimum of 20 centimeters (cm) from the anal verge as determined by baseline endoscopy (flexible sigmoidoscopy or colonoscopy) performed during screening, 4-16 days prior to Day 1
- Naive to treatment with any anti-TNF therapy
- Participants must have had an inadequate response, loss of response, or intolerance to prior corticosteroid and/or immunosuppressant treatment
- Background regimen for UC may include oral 5-aminosalicylate (5-ASA), oral corticosteroids, budesonide, probiotics, azathioprine (AZA), 6-mercaptopurine (6-MP), or methotrexate (MTX) if doses have been stable during the screening period
- Use of highly effective contraception
- Must have received a colonoscopy within the past year or be willing to undergo a colonoscopy in lieu of a flexible sigmoidoscopy at screening

Exclusion Criteria:

- A history of or current conditions and diseases affecting the digestive tract, such as indeterminate colitis, suspicion of ischemic colitis, radiation colitis, or microscopic colitis, Crohn's disease, fistulas or abdominal abscesses, colonic mucosal dysplasia, intestinal obstruction, toxic megacolon, or unremoved adenomatous colonic polyps
- Prior or planned surgery for UC
- Past or present ileostomy or colostomy
- Any prior treatment with etrolizumab or other anti-integrin agents (including natalizumab, vedolizumab, and efalizumab) as stated in the protocol
- Any prior treatment with anti-adhesion molecules (such as mucosal addressin cell adhesion molecule [MAdCAM-1])
- Any prior treatment with rituximab
- Any treatment with tofacitinib during screening
- Congenital or acquired immune deficiency, chronic hepatitis B or C infection, human immunodeficiency virus (HIV) positive, or history of tuberculosis (active or latent)
- Evidence of or treatment for *Clostridium difficile* within 60 days prior to Day 1 or other intestinal pathogens within 30 days prior to Day 1
- History of recurrent opportunistic infections and/or severe disseminated viral infections
- History of organ transplant
- Any major episode of infection requiring treatment with intravenous (IV) antibiotics within 8 weeks prior to screening or oral antibiotics within 4 weeks prior to screening
- Received a live attenuated vaccine within 4 weeks prior to Day 1