ForPatients
by Roche

Ulcerative Colitis

A Study of the Efficacy and Safety of Etrolizumab in Ulcerative Colitis Participants Who Have Been Previously Exposed to Tumor Necrosis Factor (TNF) Inhibitors

A Study of the Efficacy and Safety of Etrolizumab in Participants With Ulcerative Colitis Who Have Been Previously Exposed to Tumor Necrosis Factor (TNF) Inhibitors

Trial Status	Trial Runs In	Trial Identifier
Completed	24 Countries	NCT02100696 2013-004278-88 GA28950

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, Double-Blind, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of Etrolizumab During Induction and Maintenance in Patients With Moderate to Severe Active Ulcerative Colitis Who Have Been Previously Exposed to TNF Inhibitors

Trial Summary:

This Phase III, double-blind, placebo-controlled, multicenter study will investigate the efficacy and safety of etrolizumab during induction and maintenance of remission compared with placebo in the treatment of participants with moderately to severely active ulcerative colitis (UC) who have been previously exposed to TNF inhibitors.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT02100696 2013-004278-88 GA28950
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 80 Years	No

Inclusion Criteria:

- Diagnosis of UC established at least 3 months prior to Day 1
- Moderately to severely active UC as determined by the Mayo Clinic Score (MCS) assessment
- Treatment within 5 years prior to screening with one or two induction regimens that contain TNF inhibitors (including TNF inhibitor biosimilars)
- Washout of anti-TNF therapy for at least 8 weeks preceding Day 1
- Background regimen for UC may include oral 5-aminosalicylic acid (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 as defined by the protocol
- 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)
- Any prior treatment with anti-adhesion molecules (e.g. anti-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 or clinically significant cytomegalovirus (CMV) colitis within 60 days prior to Day 1
- Evidence of or treatment for 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