ForPatients
by Roche

Colite Ulcerativa

LAUREL - Estudo de fase III, randomizado, duplo-cego, controlado por placebo e multicêntrico para avaliar a eficácia (manutenção da remissão) e segurança do etrolizumabe comparado ao placebo em pacientes com Colite Ulcerativa ativa, de moderada a grave, não tratados anteriormente com inibidores de TNF

Trial Status	Trial Runs In	Trial Identifier
Concluído	15 Countries	NCT02165215 2013-004280-31 GA29102

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

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:

Esse é um estudo multicêntrico, de fase III, randomizado, duplo-cego, de grupos paralelos, para avaliar a segurança, eficácia e tolerância de etrolizumabe (105 mg SC Q4W) comparado ao placebo no tratamento de UC. A segurança e a eficácia do tratamento contínuo com etrolizumabe serão avaliadas em participantes que atingirem uma resposta clínica após 10 semanas.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02165215 2013-004280-31 GA29102
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- 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
- Cogenital 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