ForPatients
by Roche

Ulcerative Colitis

How does a new medicine (efmarodocokin alfa) compare to available medicine and placebo – in people with ulcerative colitis

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT03558152 2017-002350-36 GA39925

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:

A Phase II, Randomized, Parallel-Group, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study To Evaluate the Efficacy, Safety, and Pharmacokinetics of UTTR1147A Compared With Placebo and Compared With Vedolizumab in Patients With Moderate to Severe Ulcerative Colitis

Trial Summary:

This phase 2, randomized, double-blind, placebo-controlled, parallel-group clinical trial – was done to study “efmarodocokin alfa”, a new medicine for the treatment of patients with ulcerative colitis (UC). This study compared how well efmarodocokin alfa works in comparison to vedolizumab and placebo – when given to people with UC. One hundred and ninety-five people took part at 71 study centers in 16 countries.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 2
Sponsor	Phase

NCT03558152 2017-002350-36 GA39925
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Diagnosis of UC
- Confirmation of moderately to severely active UC, defined by the Mayo Clinic Score

- Inadequate response, loss of response, or intolerance to prior immunosuppressant treatment (i.e., azathioprine, 6-mercaptopurine, methotrexate, or tumor necrosis factor [TNF] inhibitors [maximum of 2 prior TNF inhibitors]) and/or corticosteroid treatment
- Use of highly effective contraception as defined by the protocol

Exclusion Criteria:

- History of psoriasis or psoriatic arthritis; any other inflammatory skin disorders requiring oral corticosteroids, immunosuppressants, or biological therapy within the previous year; or primary sclerosing cholangitis
- History of cancer as defined by the protocol
- Significant uncontrolled comorbidity, such as cardiac, pulmonary, renal, hepatic, endocrine, or gastrointestinal disorders (excluding UC)
- Prior extensive colonic resection, subtotal or total colectomy, or proctocolectomy, or planned surgery for UC
- Diagnosis of indeterminate colitis or granulomatous (Crohn's) colitis or toxic megacolon within 12 months prior to screening
- Suspicion of ischemic colitis, radiation colitis, or microscopic colitis
- Current fistula or history of fistula, pericolonic abscess and stricture (stenosis) of the colon
- History or current evidence of unresectable colonic mucosal dysplasia or history of high-grade colonic mucosal dysplasia
- Prior treatment with UTTR1147A
- Prior treatment with vedolizumab, etrolizumab, natalizumab, efalizumab, or any other anti-integrin agents
- Prior treatment with rituximab
- Use of prohibited therapies, as defined by the protocol, prior to randomization
- Congenital or acquired immune deficiency
- Evidence or treatment of infections or history of infections, as defined by the protocol