ForPatients
by Roche

Ulcerative Colitis

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of UTTR1147A Compared With Placebo and With Vedolizumab in Participants With Moderate to Severe Ulcerative Colitis (UC)

Trial Status	Trial Runs In	Trial Identifier
Completed	16 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

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- 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

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