ForPatients
by Roche

Morbus CrohnColitis Ulcerosa

Eine Verlängerungsstudie zur Beurteilung der Langzeitsicherheit und Verträglichkeit von UTTR1147A bei Teilnehmenden mit mittelschwerer bis schwerer Colitis ulcerosa oder Morbus Crohn

An Extension Study to Evaluate the Long-Term Safety and Tolerability of UTTR1147A in Participants With Moderate to Severe Ulcerative Colitis or Crohn's Disease

Trial Status	Trial Runs In	Trial Identifier
Beendet	14 Countries	NCT03650413 2017-004997-32 GA40209

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

Official Title:

A Phase II Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of UTTR1147A in Patients With Moderate to Severe Ulcerative Colitis or Crohn's Disease

Trial Summary:

This clinical trial was done to study a new medicine called, “efmarodocokin alfa”, for the treatment of patients with ulcerative colitis. This was a Phase 2 open-label extension study to find out the long-term safety and tolerability of efmarodocokin alfa in patients with moderate to severe ulcerative colitis. It was carried out at 66 study centers in fourteen countries.

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

NCT03650413 2017-004997-32 GA40209
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

Inclusion Criteria for Study Entry:

- Prior enrollment in Study GA29469 or Study GA39925 and meeting protocol defined entry criteria

Inclusion Criteria for Study Entry and Study Re-Entry:

- Ability to comply with requirements of the study, in the investigator's judgment
- For women and men: use of highly effective contraception as defined by the protocol.

Exclusion Criteria:

Exclusion Criteria for Study Entry:

- Withdrawal of consent from parent study
- Discontinuation of study drug as required by the parent study protocol
- Discontinuation of study drug and withdrawal from Study GA29469 prior to Day 85 or from Study GA39925 prior to Week 8
- Noncompliance in the parent study, specifically defined as missing scheduled visits or non-adherence with background medications and concomitant medications

Exclusion Criteria for Study Entry and Study Re-Entry:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 8 weeks after the final dose of study drug or within 18 weeks after the final dose of study drug from GA39925, whichever is longer
- Any new malignancy, significant uncontrolled comorbidity, such as cardiac, pulmonary, renal, hepatic, endocrine, or gastrointestinal disorders, or signs or symptoms of infection judged by the investigator to be clinically significant since enrolling in the parent study
- Use of prohibited therapies as defined in the parent study
- Abnormal laboratory values, as defined in the protocol, recorded at the last visit in the parent study

Exclusion Criterion for Study Re-Entry:

- Use of prohibited concomitant therapy since enrolling in the extension study