ForPatients
by Roche

Ulcerative Colitis

Study for Participants With Ulcerative Colitis Previously Enrolled in Etrolizumab Phase II/III Studies

Trial Status	Trial Runs In	Trial Identifier
Terminated	42 Countries	NCT02118584 2013-004435-72 GA28951

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:

An Open-Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis Patients Previously Enrolled in Etrolizumab Phase II/III Studies

Trial Summary:

This two-part, part 1: open-label extension (OLE) and part 2: safety monitoring (SM) study will examine the efficacy and safety of continued etrolizumab treatment in moderate to severe ulcerative colitis (UC) participants previously enrolled in etrolizumab Phase II/III studies. Participants with moderate to severe UC who were enrolled in the Phase II OLE study (GA27927 [NCT01461317]) or the Phase III studies (GA28948 [NCT02163759], GA28949 [NCT02171429], GA28950 [NCT02100696], GA29102 [NCT02165215], and GA29103 [NCT02136069]) were included. Participants from the Phase II OLE study or the Phase III studies who are not eligible or willing to receive etrolizumab in the OLE-SM study, and who have completed the 12-week safety follow-up period will be enrolled in Part 2. Part 1 of OLE-SM will continue for up to 9 years after the first participant is enrolled into the study. Following Part 1, participants will enter Part 2 for a period of 92 weeks.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02118584 2013-004435-72 GA28951
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

Part 1 (Open-label Extension)

- Participants previously enrolled in the Phase II OLE study or Phase III controlled studies who meet the eligibility criteria for open-label etrolizumab for those studies as described in the protocol

Part 2 (Safety Monitoring)

- Participants whose safety follow-up or PML follow-up is not completed within Study GA27927 and participants who had their last dose of etrolizumab in July 2016 in Study GA27927 and are not eligible or willing to enroll in Part 1 (OLE)
- Participants who participated in one of the etrolizumab Phase III studies and are not eligible or willing to enter Part 1 (OLE)
- Participants who transfer from Part 1 (OLE)
- Completion of the 12-week safety follow-up prior to entering.

Exclusion Criteria:

Part 1 (Open-label Extension)

- Withdrawal of consent from and participant not compliant in the Phase II OLE study or any of the Phase III studies
- Participant who discontinued etrolizumab/etrolizumab placebo prior to Week 10 or did not perform the Week 10 visit of the Phase III Studies GA28948, GA28949, GA29102, and GA29103
- Participant who discontinued etrolizumab/etrolizumab placebo prior to Week 14 or did not perform the Week 14 visit of the Phase III Study GA28950
- Any new, significant, uncontrolled condition