

Ulcerative Colitis

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

Trial Status
Active, not recruiting

Trial Runs In
44 Countries

Trial Identifier
NCT02118584 2013-004435-72
GA28951

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥ 18 Years

Healthy Volunteers
No