ForPatients
by Roche

Morbus Crohn

Offene Verlängerungs- und Sicherheitsstudie für Patient*innen mit Morbus Crohn, die zuvor an der Etrolizumab-Phase-III-Studie GA29144 teilgenommen hatten

Open-Label Extension and Safety Study for Patients With Crohn's Disease Previously Enrolled in the Etrolizumab Phase III Study GA29144

Trial Status	Trial Runs In	Trial Identifier
Beendet	33 Countries	NCT02403323 2014-003855-76 GA29145

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

Official Title:

An Open-Label Extension and Safety Monitoring Study of Patients With Moderately to Severely Active Crohn's Disease Previously Enrolled in the Etrolizumab Phase III Protocol GA29144

Trial Summary:

This open-label extension and safety monitoring study is composed of two parts: Part 1 will evaluate the long-term safety and efficacy of continued etrolizumab treatment in participants with moderately to severely active Crohn's disease who were previously enrolled in the etrolizumab Phase III Study GA29144 (NCT02394028) and who meet eligibility criteria for enrollment into Part 1. In Part 2, participants who have stopped etrolizumab treatment (either by exiting Part 1 of this study or by entering directly from Study GA29144 [NCT02394028]) will be monitored for 92 weeks for progressive multifocal leukoencephalopathy (PML) and other safety events.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02403323 2014-003855-76 GA29145
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

Part 1 Open-Label Extension:

- Patients previously enrolled in etrolizumab Phase III study GA29144 (NCT02394028) who meet the eligibility criteria for open-label etrolizumab as described in the protocol

Part 2 Safety Monitoring:

- Patients who participated in etrolizumab Phase III study GA29144 (NCT02394028) and are not eligible or choose not to enter Part 1
- Patients who transfer from Part 1
- Completion of the 12-week safety follow-up period prior to entering

Exclusion Criteria:

Part 1 Open-Label Extension:

- Any new, significant, uncontrolled condition

Part 2 Safety Monitoring:

- No exclusion criteria