ForPatients

by Roche

Ulcerative Colitis

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

Trial Status Trial Runs In Trial Identifier

Recruiting 16 Countries NCT06137183 2023-506655-19-00

GA44839

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, Multicenter Induction Study With an Active Treatment Extension to Evaluate the Efficacy, Safety, and Pharmacokinetics of Vixarelimab in Patients With Moderate to Severe Ulcerative Colitis

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety, and pharmacokinetics (PK) of vixarelimab compared with placebo in participants with moderate to severe UC who have demonstrated inadequate response to, loss of response to, or intolerance to prior conventional or advanced therapy.

Genentech, Inc. Sponsor		Phase 2 Phase	
NCT06137183 2023-506655-19 Trial Identifiers			
Eligibility Criteria:			
Gender All	Age #18 Years		Healthy Volunteers

Inclusion Criteria:

- Diagnosis of UC for at least 3 months
- Moderately to severely active UC, assessed by mMS
- Inadequate response, loss of response to, or intolerance to conventional or advanced therapies for UC

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Exclusion Criteria:

- Diagnosis of Crohn's disease or indeterminate colitis
- Suspicion of ischemic, radiation, microscopic, or infectious colitis
- Prior colectomy
- Inadequate response or loss of response to previous treatment of UC with tofacitinib, upadacitinib, or other systemic janus kinase (JAK) inhibitor