ForPatients
by Roche

Ulcerative Colitis

A Study to Evaluate the Efficacy and Safety of PF-06480605 in Adults With Moderate to Severe Ulcerative Colitis

Trial Status	Trial Runs In	Trial Identifier
Completed	23 Countries	NCT04090411 TL1A Tuscany 2 2019-002698-74 B7541007

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 2B, Multicenter, Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study to Evaluate The Efficacy, Safety, and Pharmacokinetics of PF-06480605 in Adult Participants With Moderate To Severe Ulcerative Colitis

Trial Summary:

This phase 2b study is designed to have all subjects go into a 12 week induction period to compare different doses of study drug against placebo. After induction is complete all subjects will receive active therapy for 40 weeks, followed by a 12 week follow up period.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04090411 TL1A Tuscany 2 2019-002698-74 B7541007
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

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- A diagnosis of UC for #3 months.
- Participants with moderate to severe active UC as defined by a Total Mayo Score of

#6, and an endoscopic subscore of #2.

- Active disease beyond the rectum (>15 cm of active disease from the anal verge at the screening endoscopy).
- Must have failed or been intolerant to at least one of the following class of medications: steroids, immunosuppressants, anti-TNFs, anti-integrin inhibitors, anti- IL-12/23 inhibitors, or JAK inhibitors.

Exclusion Criteria:

- Participants with a diagnosis of ischemic colitis, infectious colitis, radiation colitis, microscopic colitis, indeterminate colitis, or findings suggestive of Crohn's disease (eg, skip lesions, fistulae/perianal disease, non-necrotizing granulomas, etc.).
- Participants with an imminent need for surgery or with elective surgery scheduled to occur during the study
- Chest Radiograph showing abnormalities: The study will accept a Chest x-ray or computed tomography scan of the chest examination performed up to 12 weeks prior to screening if available.
- 12-lead electrocardiogram (ECG) that demonstrates clinically relevant abnormalities that may affect participant safety or interpretation of study results
- Infected with tuberculosis, (TB): Any evidence of untreated latent or active TB infection.
- Infected with human immunodeficiency virus, (HIV), Hepatitis B or C viruses