

Ulcerative Colitis

A Study to Assess the Efficacy and Safety of Subcutaneous Induction Therapy with Afimkibart in Participants With Moderately to Severely Active Ulcerative Colitis (AMETRINE-SC)

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07846683 CA46523

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 III, Multicenter, Double-Blind Placebo-Controlled Study to Assess the Efficacy and Safety of Subcutaneous Induction Therapy With Afimkibart in Patients With Moderately to Severely Active Ulcerative Colitis

Trial Summary:

The purpose of this study is to assess the efficacy and safety of subcutaneous induction with afimkibart in participants with moderately to severely active ulcerative colitis (UC).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT07846683 CA46523
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#16 Years & # 80 Years

Healthy Volunteers
No

Inclusion Criteria:

- Confirmed diagnosis of UC.
- Moderately to severely active UC assessed by modified Mayo Score (mMS).
- Bodyweight $\geq$ 40 kilogram (kg).
- Up to date with colorectal cancer (CRC) screening performed according to local standards.
- Demonstrated inadequate response, loss of response and/or intolerance to at least one protocol-specified conventional or advanced UC therapy.

- Females of childbearing potential must meet protocol criteria for contraception requirements.

Exclusion Criteria:

- Currently known complications of UC (e.g. fulminant colitis, toxic megacolon).
- Current diagnosis of Crohn's disease (CD) or indeterminate colitis, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis.
- Presence of an ostomy or ileoanal pouch.
- Current diagnosis or suspicion of primary sclerosing cholangitis.
- Pregnancy or breastfeeding, or intention of becoming pregnant during the study.
- Past or current evidence of definite low-grade or high-grade colonic dysplasia or adenomas or neoplasia not completely removed.
- History of malignancy within 5 years, with the exception of malignancies adequately treated with resection for non-metastatic basal cell or squamous cell cancer or in situ cervical cancer.
- Evidence of infection with *Clostridioides difficile* (*C. difficile*; formerly known as *Clostridium difficile*), cytomegalovirus (CMV), human immunodeficiency virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV).
- Has evidence of active tuberculosis (TB), latent TB not successfully treated (per local guidance) or inadequately treated TB.
- Has received protocol-specified prohibited medicines, including known exposure to any type of anti-TL1A therapy.