ForPatients
*by Roche*

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 | Trial Runs In | Trial Identifier |
|---|---|---|
| Not yet recruiting | | 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).

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|---|---|
| **Hoffmann-La Roche**<br>Sponsor | **Phase 3**<br>Phase |

**NCT07846683 CA46523**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #16 Years & # 80 Years | No |

## *Inclusion Criteria:*

- Confirmed diagnosis of UC.
- Moderately to severely active UC assessed by modified Mayo Score (mMS).
- Bodyweight >= 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.

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- 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.

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