

A Study to Assess the Pharmacokinetics, Effectiveness and Safety of Afimkibart for Induction and Maintenance Therapy in Children With Moderately to Severely Active Crohn's Disease

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07298421 2025-523318-96-00
CP45906

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 Randomized Double-Blind Multi-Center Treat-Through Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Induction and Maintenance Therapy With Afimkibart (RO7790121) in Children Aged 2-17 Years With Moderately to Severely Active Crohn's Disease

Trial Summary:

This phase III, double-blind, multi-center treat-through study will evaluate the efficacy and safety of Afimkibart (also known as RO7790121) in children with moderately to severely active Crohn's Disease (CD).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#2 Years & # 17 Years

Healthy Volunteers
No

Inclusion Criteria:

- Body weight $\geq$ 10 kilogram (kg)
- Active CD confirmed by endoscopy (ileocolonoscopy)

ForPatients

by Roche

- Moderately to severely active CD, defined as a Pediatric Crohn's Disease Activity Index (PCDAI) score ≥ 30 , and Simple Endoscopic Score Crohn's Disease (SES-CD) ≥ 6 (or ≥ 4 for isolated ileal disease) confirmed through centrally-read ileocolonoscopy
- Inadequate response, loss of response, and/or intolerance to at least one of the following conventional therapies (aminosalicylates, corticosteroids and/or immunosuppressants) or advanced therapies (including anti-tumor necrosis factor, anti-interleukin, anti-integrin, or Janus Kinase (JAK) inhibitors)

Exclusion Criteria:

- Monogenic disorder pertaining to infant onset Inflammatory Bowel Disease (IBD)
- History of ≥ 3 bowel resections: > 2 missing segments of the following five segments: terminal ileum, right colon, transverse colon, sigmoid and left colon, and rectum
- Current diagnosis of ulcerative colitis (UC), abdominal/intraabdominal/perianal fistula and/or abscess, indeterminant colitis, IBD-unclassified, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis, or active diverticular disease.
- Symptomatic bowel strictures, fulminant colitis, or toxic megacolon
- Presence of abdominal or perianal abscess
- Current diagnosis or suspicion of primary sclerosing cholangitis