ForPatients
by Roche

Crohn's DiseaseUlcerative Colitis

A Phase I Study of Etrolizumab Followed by Open-Label Extension and Safety Monitoring in Pediatric Patients With Moderate to Severe Ulcerative Colitis or Moderate to Severe Crohn's Disease

Trial Status	Trial Runs In	Trial Identifier
Terminated	4 Countries	NCT03478956 2017-003649-10 CA40192

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase I, Open-Label, Randomized, Pharmacokinetic, Pharmacodynamic, and Safety Study of Etrolizumab Followed by Open-Label Extension and Safety Monitoring in Pediatric Patients From 4 Years to Less Than 18 Years Of Age With Moderate to Severe Ulcerative Colitis or Moderate To Severe Crohn's Disease

Trial Summary:

This study will evaluate pharmacokinetics, pharmacodynamics and safety of etrolizumab in pediatric patients of 4 to <18 years of age with moderate to severe ulcerative colitis (UC) or with moderate to severe Crohn's disease (CD).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT03478956 2017-003649-10 CA40192
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 4 Years & # 17 Years	No

Inclusion Criteria:

- Age of 4 years to <18 years at the time of signing the Informed Consent Form.
- Weight of 13 kilograms (kg) or more

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- Diagnosis of ulcerative colitis (UC) or Crohn's Disease (CD) confirmed by biopsy and established for #3 months (i.e., after first diagnosis by a physician according to American College of Gastroenterology [ACG] guidelines) prior to screening
- Inadequate response, loss of response or intolerance to prior immunosuppressants and/or corticosteroid treatment and/or anti-tumor necrosis factor (TNF) therapy
- For postpubertal females of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraceptive methods during the treatment period and for at least 24 weeks after the last dose of etrolizumab.
- For male patients: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm

Exclusion Criteria:

- Pregnant or lactating
- Lack of peripheral venous access
- Congenital or acquired immune deficiency
- Neurological conditions or diseases that may interfere with monitoring for progressive multifocal leukoencephalopathy (PML)
- History of demyelinating disease
- History of cancer, including hematologic malignancy, solid tumors, and carcinoma in situ, within 5 years before screening

Exclusion Criteria Related to Inflammatory Bowel Disease:

- Prior extensive colonic resection, subtotal or total colectomy, or planned surgery
- Past or present ileostomy or colostomy
- Diagnosis of indeterminate colitis
- Suspicion of ischemic colitis, radiation colitis, or microscopic colitis
- Diagnosis of toxic megacolon within 12 months of initial screening visit
- Abdominal abscess
- A history or current evidence of colonic mucosal dysplasia
- Patients with fixed symptomatic stenosis of the intestine
- Patients with history or evidence of adenomatous colonic polyps that have not been removed

Exclusion Criteria Related to Ulcerative Colitis:

- Severe extensive colitis per investigator judgment that colectomy is imminent

Exclusion Criteria Related to Crohn's Disease:

- Sinus tract with evidence for infection (e.g., purulent discharge) in the clinical judgment of the investigator
- Short-bowel syndrome
- Evidence of abdominal or perianal abscess
- Expected to require surgery to manage CD-related complications during the study

Exclusion Criteria Related to Prior or Concomitant Therapy:

- Any prior treatment with anti-integrin agents (including natalizumab, vedolizumab, and efalizumab), ustekinumab, anti-adhesion molecules (e.g., anti-MAdCAM-1), or rituximab
- Use of IV steroids within 30 days prior to screening with the exception of a single administration of IV steroid

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- Use of agents that deplete B or T cells (e.g., alemtuzumab or visilizumab) within 12 months prior to Day 1, with the exception of AZA and 6-MP
- Use of cyclosporine, tacrolimus, sirolimus, or mycophenolate mofetil (MMF) within 4 weeks prior to Day 1
- Use of other biologics (e.g. anti-TNF) within 8 weeks before dosing (unless drug level is below detectability before completion of the 8-week interval)
- Chronic nonsteroidal anti-inflammatory drug (NSAID) use
- Patients who are currently using anticoagulants
- Apheresis (i.e., Adacolumn apheresis) within 2 weeks prior to Day 1
- Received any investigational treatment including investigational vaccines within 12 weeks prior to Day 1 of the study or 5 half-lives of the investigational product, whichever is greater
- History of moderate or severe allergic or anaphylactic/anaphylactoid reactions to chimeric, human, or humanized antibodies, fusion proteins, or murine proteins or hypersensitivity to etrolizumab (active drug substance) or any of the excipients (L-histidine, L-arginine, succinic acid, polysorbate 20)

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