ForPatients
by Roche

Ulcerative Colitis

A study in the use of etrolizumab in patients with ulcerative colitis (Eucalyptus)

Evaluate the Efficacy and Safety of rhuMAb Beta7 in Patients With Moderate to Severe Ulcerative Colitis

Trial Status	Trial Runs In	Trial Identifier
Completed	11 Countries	NCT01336465 GP27778 ABS4986g

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:

Phase II Randomized Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of rhuMAb Beta7 in Patients With Moderate to Severe Ulcerative Colitis

Trial Summary:

This Phase II study is a randomized, double-blind, placebo-controlled multicenter study to evaluate the efficacy and safety of rhuMAb Beta7 in patients with moderate to severe ulcerative colitis.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT01336465 GP27778 ABS4986g
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Diagnosis of moderate to severe ulcerative colitis outpatient
- Disease duration at time of screening of >/= 12 weeks

Exclusion Criteria:

- Extensive colonic resection or subtotal or total colectomy
- Presence of an ileostomy or colostomy
- Moderate to severe anemia
- A history or evidence of colonic mucosal dysplasia
- Pregnant or lactating
- Significant uncontrolled co-morbidity, such as neurological, cardiac, pulmonary, renal, hepatic, endocrine, or gastrointestinal (GI) disorders
- Significant screening ECG abnormalities, including evidence of acute myocardial infarction, complete left bundle branch block, second-degree heart block, or complete heart block
- Poorly controlled diabetes
- Impaired renal function
- Impaired hepatic function in the absence of a diagnosis of primary sclerosing cholangitis
- Positive tests for antibodies indicating active or prior infection with HIV or hepatitis B (HBV) or C (HCV)
- Positive screening test for latent mycobacterium tuberculosis (TB) infection
- Demyelinating disease
- Received any investigational treatment within 12 weeks prior to initiation of study treatment
- Previous exposure to rhuMAb Beta7