

Relapsed or Refractory Multiple MyelomaHealthy Volunteers

A Clinical Study to Evaluate the Effects of RO7875913 in Healthy Participants and of RO7875913 With Cevostamab in Participants With Relapsed/Refractory Multiple Myeloma

A Dose-Escalation Study of RO7875913 in Healthy Participants

Trial Status
Active, not recruiting

Trial Runs In
1 Country

Trial Identifier
NCT07342114 2026-526130-15-00
GO46451

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 Ia/Ib, Multicenter, Dose-Escalation and Expansion Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of RO7875913 in Healthy Volunteers and to Assess Its Preliminary Activity in Combination With Cevostamab In Patients With Relapsed Or Refractory Multiple Myeloma

Trial Summary:

Part A: The purpose of Part A of this study is to evaluate the safety, pharmacokinetics, and pharmacodynamics of RO7875913 in healthy participants. Part B: The purpose of Part B of this study is to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary clinical activity of RO7875913 administered in combination with the T cell-engaging bispecific antibody (TCB) cevostamab in participants with relapsed or refractory (R/R) multiple myeloma (MM).

Genentech, Inc.
Sponsor

Phase 1
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years & # 65 Years

Healthy Volunteers
Accepts Healthy Volunteers

Inclusion Criteria:

ForPatients

by Roche

General:

- Agreement to adhere to the contraception requirements

Part A:

- Body weight > 40 kilogram (kg) with a body mass index of 18-30 kg per meter square (kg/m²)

Part B:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy of at least 12 weeks
- Agreement to provide bone marrow biopsy and aspirate samples

Exclusion Criteria:

General:

- Treatment with any vaccine within 4 weeks prior to initiation of study drug, or vaccination scheduled to occur during the study
- History or current cardiovascular or pulmonary disease that may limit the ability to respond to systemic infusion/injection reactions
- Positive test result for hepatitis B surface antigen, hepatitis C virus (HCV), or human immunodeficiency virus (HIV) antibody screen
- History of any malignancy
- Major surgical procedure within 28 days prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- History or clinical manifestations of significant metabolic, hepatic, renal, pulmonary, cardiovascular, hematologic, gastrointestinal, urologic, neurologic, or psychiatric disorders
- Known allergy or hypersensitivity to any component of the RO7875913 formulation

Part A:

- Treatment with investigational biologic therapy (or blinded comparator) within 90 days or 5 drug elimination half-lives, whichever is longer, prior to initiation of study drug
- Treatment with investigational non-biologic therapy (or blinded comparator) within 28 days or 5 drug elimination half-lives, whichever is longer, prior to initiation of study drug
- Clinically apparent or familial history of autoimmune disease

Part B:

- Treatment with any systemic chemotherapeutic agent, or treatment with any other anti-cancer agent (investigational or otherwise) within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to first dose of study treatment
- Treatment with any immunosuppressive medication within 2 weeks prior to first dose of study treatment
- Absolute plasma cell count exceeding 500/mL or 5% of the peripheral blood white cells