ForPatients
by Roche

Relapsed or Refractory Multiple Myeloma

A Study Evaluating the Safety, Pharmacokinetics, and Activity of the Combination of Cevostamab and Elranatamab in Participants With Relapsed or Refractory Multiple Myeloma (R/R MM)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	NCT05927571 2023-504657-13-00 GO43979

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:

An Open-Label, Multicenter, Phase Ib Trial Evaluating the Safety, Pharmacokinetics, and Activity of the Combination of Cevostamab and Elranatamab in Patients With Relapsed or Refractory Multiple Myeloma

Trial Summary:

The purpose of the study is to evaluate safety and tolerability of the combination of cevostamab plus elranatamab and also determine the recommended Phase II dose (RP2D) for the study treatment. The study consists of a safety lead-in stage, and an expansion stage.

Genentech, Inc.
Sponsor

Phase 1
Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Diagnosis of R/R MM per IMWG criteria
- For female participants of childbearing potential: agreement to remain abstinent or use contraception
- For male participants: agreement to remain abstinent or use a condom

Exclusion Criteria:

- Prior treatment with cevostamab or another agent targeting fragment crystallizable receptor-like 5 (FcRH5)
- Prior treatment with elranatamab
- Prior allogeneic stem cell transplantation (SCT)
- Absolute plasma cell count exceeding 500 per milliliter (mL) or 5% of the peripheral blood white cells
- Diagnosis of Waldenström macroglobulinemia or polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, skin changes (POEMS) syndrome
- Participants with known history of amyloidosis
- History of autoimmune disease
- History of confirmed progressive multifocal leukoencephalopathy
- Peripheral motor polyneuropathy of prespecified grade
- Known or suspected chronic cytomegalovirus (CMV) and/or Epstein-Barr virus (EBV) infection
- Known history of hemophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
- Acute or chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Human immunodeficiency virus (HIV) seropositivity
- History of central nervous system (CNS) myeloma disease
- Significant cardiovascular disease