ForPatients
by Roche

Multiple Myeloma

Dose-Escalation Study of BFCR4350A in Participants With Relapsed or Refractory Multiple Myeloma (R/R MM)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	4 Countries	NCT03275103 GO39775

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 I Trial Evaluating the Safety and Pharmacokinetics of Escalating Doses of Cevostamab (BFCR4350A) in Patients With Relapsed or Refractory Multiple Myeloma

Trial Summary:

This is a phase I, multicenter, open-label, dose-escalation study of cevostamab administered as a single agent by IV infusion to participants with relapsed or refractory multiple myeloma (R/R MM).

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03275103 GO39775
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
- Life expectancy of at least 12 weeks
- Participants must have relapsed or refractory (R/R) multiple myeloma (MM) for which no established therapy for MM is appropriate and available or be intolerant to those established therapies
- Adverse events from prior anti-cancer therapy resolved to Grade < or = 1, except any grade alopecia and/or peripheral sensory or motor neuropathy which must have resolved to Grade < or = 2
- Measurable disease defined by laboratory test results

- Female participants of childbearing age must agree to remain abstinent or use reliable contraceptive methods during the treatment period, and at least 5 months after last dose of study drug. Women must refrain from breastfeeding during the same period.
- Male participants must agree to refrain from donating sperm, to abstain or use a condom during the treatment period, and for at least 2 months after the last dose of tocilizumab (if applicable).

Exclusion Criteria:

- Inability to comply with protocol-mandated hospitalization and activities restrictions
- Pregnant or breastfeeding, or planning to become pregnant during the study or within 5 months after the last dose of cevostamab or within 3 months after the last dose of of tocilizumab (if applicable)
- Prior use of any monoclonal antibody, radioimmunoconjugate, or antibody-drug conjugate as anti-cancer therapy within 4 weeks before first infusion
- Prior treatment with systemic immunotherapeutic agents within 12 weeks or 5 half-lives of the drug, whichever is shorter, before first infusion
- Prior treatment with chimeric antigen receptor (CAR) T-cell therapy within 12 weeks before first cevostamab infusion
- Known treatment-related, immune-mediated adverse events associated with prior immunotherapeutic agents
- Treatment with radiotherapy, any 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 cevostamab infusion
- Autologous stem cell transplantation (SCT) within 100 days prior to first infusion
- Prior allogeneic SCT or solid organ transplantation
- Absolute plasma cell count exceeding 500/micro L or 5% of the peripheral blood white cells
- History of autoimmune disease or of confirmed progressive multifocal leukoencephalopathy
- Known history of hemophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapy (or recombinant antibody-related fusion proteins)
- Patients with known history of amyloidosis (e.g., positive Congo Red stain or equivalent in tissue biopsy)
- Patients with lesions in proximity of vital organs that may develop sudden decompensation/ deterioration in the setting of a tumor flare
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Current or past history of central nervous system (CNS) disease, or CNS involvement by MM
- Significant cardiovascular disease that may limit a patient's ability to adequately respond to a CRS event
- Symptomatic active pulmonary disease requiring supplemental oxygen
- Within 14 days prior to first cevostamab infusion: known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment, or any major episode of infection requiring treatment with IV antibiotics within 4 weeks prior to first infusion
- Positive and quantifiable Epstein-Barr virus (EBV) polymerase chain reaction (PCR) or cytomegalovirus (CMV) PCR prior to first study treatment
- Known or suspected chronic active EBV infection, acute or chronic hepatitis C virus (HCV) infection
- Positive serologic or PCR test results for acute or chronic hepatitis B virus (HBV) infection
- Recent major surgery within 4 weeks prior to first infusion
- Human Immunodeficiency Virus (HIV) positive
- Any episode of active, symptomatic COVID-19 infection, or requiring treatment with IV antivirals for COVID-19 (not including COVID-19 primary prophylaxis) within 14 days, prior to first study treatment
- Administration of a live, attenuated vaccine within 4 weeks before first cevostamab infusion or anticipation that such a live attenuated vaccine will be required during the study

- Received systemic immunosuppressive medications (including, but not limited to, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents), with the exception of corticosteroid treatment <=10 mg/day prednisone or equivalent within 2 weeks prior to first dose of cevostamab and, if applicable, tocilizumab premedication prior to first dose of cevostamab
- History of illicit drug or alcohol abuse within 12 months prior to screening
- Any medical condition or laboratory test abnormality that precludes the participant's safe participation in and completion of the study, or which could affect compliance with the protocol or interpretation of results