ForPatients
by Roche

Multiple Myeloma

A Study Evaluating the Pharmacokinetics, Safety, and Efficacy of Cevostamab in Chinese Participants With Relapsed or Refractory Multiple Myeloma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT06934044 YO43835

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 Ib, Open-Label, Single-Arm, Multicenter Trial Evaluating the Pharmacokinetics, Safety, and Efficacy of Cevostamab in Chinese Patients With Relapsed or Refractory Multiple Myeloma

Trial Summary:

This study will evaluate the pharmacokinetics (PK), safety, and efficacy of cevostamab in participants with relapsed or refractory (R/R) multiple myeloma (MM).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT06934044 YO43835
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Documented diagnosis of MM based on standard International Myeloma Working Group (IMWG) criteria
- Evidence of progressive disease based on investigators determination of response by IMWG criteria on or after their last dosing regimen
- Current relapsed or refractory (R/R) disease status
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy of at least 12 weeks

- Agreement to protocol-specified assessments, including bone marrow biopsy and aspirate samples as detailed in the protocol
- Resolution of AEs from prior anti-cancer therapy to Grade =< 1 or better
- For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception during the treatment period and for at least 5 months after the final dose of cevostamab and for 3 months after the last dose of tocilizumab was administered
- For male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agree to refrain from donating sperm during the treatment period and for at least 2 months after the final dose of tocilizumab (if applicable) to avoid exposing the embryo

Exclusion Criteria:

- Unable to comply with protocol-mandated hospitalization
- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 5 months after the final dose of cevostamab or tocilizumab or within 3 months after the last dose of tocilizumab (if applicable)
- Prior treatment with cevostamab or another agent with the same target
- Prior use of any monoclonal antibody (mAb), radioimmunoconjugate, or ADC as anti-cancer therapy within 4 weeks before first study treatment, except for the use of non-myeloma therapy
- Prior treatment with systemic immunotherapeutic agents, including but not limited to, cytokine therapy and anti-CTLA-4, anti-PD-1, and anti-PD-L1
- Prior treatment with CAR-T cell therapy within 12 weeks before first cevostamab infusion
- Known treatment-related, immune-mediated adverse events associated with prior checkpoint inhibitors
- Treatment with radiotherapy, any chemotherapeutic agent, or treatment with any other anti-cancer agent within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to first study treatment
- Autologous stem cell transplantation (SCT) within 100 days prior to first study treatment
- Prior allogeneic SCT
- Prior solid organ transplantation
- History of autoimmune disease
- History of confirmed progressive multifocal leukoencephalopathy
- History of severe allergic or anaphylactic reactions to mAb therapy
- Known history of amyloidosis
- Lesions in proximity of vital organs that may develop sudden decompensation/deterioration in the setting of a tumor flare
- History of other malignancy within 2 years prior to screening, except those with negligible risk of metastasis or death, such as ductal carcinoma in situ not requiring chemotherapy, appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, low-grade, localized prostate cancer not requiring treatment or appropriately treated Stage I uterine cancer
- Current or past history of central nervous system (CNS) disease, such as stroke, epilepsy, CNS vasculitis, neurodegenerative disease, or CNS involvement by MM
- Significant cardiovascular disease that may limit a potential participant's ability to adequately respond to a cytokine release syndrome (CRS) event
- Symptomatic active pulmonary disease or requiring supplemental oxygen
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection at study enrollment, or any major episode of infection requiring treatment with IV (intravenous) antimicrobials where the last dose of IV antimicrobial was given within 14 days prior to first study treatment
- Active symptomatic COVID-19 infection at study enrollment or requiring treatment with IV antiviral where the last dose of IV antiviral treatment was given within 14 days prior to first study treatment.
- 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

- Known history of hemophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
- Known history of Grade >=3 CRS or immune effector cell-associated neurotoxicity syndrome (ICANS) with prior bispecific therapies
- Recent major surgery within 4 weeks prior to first study treatment
- Positive serologic or PCR test results for acute or chronic hepatitis B virus (HBV) infection
- Acute or chronic hepatitis C virus (HCV) infection
- Known history of human immunodeficiency virus (HIV) seropositivity
- Administration of a live, attenuated vaccine within 4 weeks before first study treatment or anticipation that such a live attenuated vaccine will be required during the study
- Treatment with systemic immunosuppressive medications, with the exception of corticosteroid treatment <= 10 mg/day prednisone or equivalent, within 2 weeks prior to first study treatment
- History of illicit drug or alcohol abuse within 12 months prior to screening, in the investigator's judgment
- Any medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study, or which could affect compliance with the protocol or interpretation of results