ForPatients
by Roche

Multiple Myeloma

A Study of Atezolizumab (Anti-Programmed Death-Ligand 1 [PD-L1] Antibody) Alone or in Combination With an Immunomodulatory Drug and/or Daratumumab in Participants With Multiple Myeloma (MM)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02431208 GO29695

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 Study of the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) Alone or in Combination With an Immunomodulatory Drug and/or Daratumumab in Patients With Multiple Myeloma (Relapsed/Refractory and Post-Autologous Stem Cell Transplantation)

Trial Summary:

This multicenter, open-label, Phase I study will evaluate the safety, efficacy, and pharmacokinetics of atezolizumab alone or in combination with daratumumab and/or various immunomodulatory agents in participants with MM who have relapsed or who have undergone autologous stem cell transplantation (ASCT). Cycle length will be 21 days in Cohorts A to C and 28 days in Cohorts D to F.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT02431208 GO29695
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Previous diagnosis of MM with objective evidence of measurable disease

- Willing and able to undergo bone marrow aspiration and biopsy tissue sample collection during screening and on study
- Eastern Cooperative Oncology Group (ECOG) performance status score less than or equal to (</=) 2
- Left ventricular ejection fraction (LVEF) greater than or equal to (>/=) 40 percent (%)
- Total bilirubin </=2 times the ULN
- Creatinine </=2.0 milligrams per deciliter (mg/dL), with creatinine clearance (CrCl) using the Cockcroft-Gault formula >/=40 milliliters per minute (mL/min) or 60 mL/min for those who receive lenalidomide
- Corrected calcium at or below ULN
- Transaminase levels </=2.5 times the upper limit of normal (ULN)
- Receipt of >/=1 but not more than 3 prior lines of therapy (Cohorts A, B, C, D1, E)
- Receipt of 2, but not more that 3 prior lines of therapy that must have included a proteasome inhibitor (PI) and immunomodulatory drug (IMiD) (alone or in combination, and are refractory to the last line of treatment(Cohort D2)
- Receipt of >/=2 prior lines of therapy and progressed on treatment with an anti-CD38 monoclonal antibody and are refractory to both a PI and IMiD (Cohort D3)
- Receipt of >/=4 lines of prior therapy and are refractory to the last line of treatment (Cohort F)
- Absolute neutrophil count (ANC) >/=1000 cells per microliter (cells/mcL) (Cohorts A, B, D, E, F)
- Platelet count >/=50,000 cells/mcL, or >/=30,000 cells/mcL if more than 50% bone marrow involvement (Cohorts A, B, D, E, F)
- All participants who are prescribed lenalidomide or pomalidomide must be counseled at a minimum of every 21-28 days about pregnancy precautions and risks of fetal exposure (Cohorts B, C, E, F)
- Agree to be registered in and comply with all requirements of the Revlimid Risk Evaluation and Mitigation Strategy (REMS) program (Cohorts B, C, E)
- Agree to be registered in and comply with all requirements of the Pomalyst REMS program (Cohort F)
- Sufficient recovery from first or second ASCT within 60-120 days of transplant (Cohort C)
- Off antibiotic/antifungal therapy for >/=14 days (Cohort C)
- Completion of any prior radiotherapy (Cohort C)
- ANC >/=1500 cells/mcL (Cohort C)

Exclusion Criteria:

- Other malignancy within 2 years prior to screening, with some exceptions
- Prior therapy with atezolizumab or other immunotherapies including CD137 agonists, anti-programmed death (PD)-1, anti-cytotoxic T-lymphocyte associated protein 4 (CTLA-4), and anti-PD-L1 therapeutic antibodies
- Uncontrolled cancer pain
- Treatment with any investigational drug within 30 days or 5 half-lives of the investigational drug, whichever is longer
- Known hypersensitivity to study drug and/or drug class
- History of autoimmune disease except for controlled, treated thyroidism or Type 1 diabetes
- Prior systemic anti-myeloma therapy within 14 days of Cycle 1 Day 1
- Prior treatment with chimeric antigen receptor (CAR) T cells or other forms of adoptive cellular therapy, with the exception of autologous stem cell transplantation
- Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes (POEMS) syndrome
- Plasma cell leukemia (greater than 2,000 cells/mcL of circulating plasma cells by standard differential)
- Immunosuppressive therapy within 6 weeks of Cycle 1 Day 1
- Daily corticosteroid requirement within 2 weeks of Cycle 1 Day 1
- Prior allogeneic stem cell transplant or solid organ transplant
- Active hepatitis B, active hepatitis C, or positive for human immunodeficiency virus (HIV)

- Uncontrolled, clinically significant pulmonary disease (for example, chronic obstructive pulmonary disease, pulmonary hypertension, idiopathic pulmonary fibrosis) that in the opinion of the investigator would put the participant at significant risk for pulmonary complications during the study
- History of pneumonitis
- Uncontrolled intercurrent illness including but not limited to uncontrolled infection, disseminated intravascular coagulation, or psychiatric illness/social situations that would limit compliance with study requirements
- Pregnant or breastfeeding females
- Inability to tolerate thromboprophylaxis (Cohorts B, C, E, F)
- Evidence of progressive MM compared to pretransplant evaluation (Cohort C)
- Prior treatment with anti-CD38 therapy including daratumumab (Cohorts D1, D2, E, F)