ForPatients
by Roche

Multiple MyelomaNon Hodgkin Lymphoma (NHL)Mature B-Cell Lymphoma

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics (PK), Pharmacodynamics (PD), and Preliminary Activity of Tiragolumab in Participants With Relapsed or Refractory Multiple Myeloma or With Relapsed or Refractory B-cell Non-Hodgkin Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Terminated	2 Countries	NCT04045028 GO41036

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 Open-Label, Multicenter Study Evaluating the Safety and Pharmacokinetics of Tiragolumab as a Single Agent and in Combination With Atezolizumab and/or Daratumumab in Patients With Relapsed or Refractory Multiple Myeloma, and as a Single Agent and in Combination With Rituximab in Patients With Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma

Trial Summary:

This is a Phase I open-label, multicenter study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary activity of tiragolumab administered as a single agent or in combination with atezolizumab and/or daratumumab or rituximab in participants with relapsed or refractory (R/R) multiple myeloma (MM) or R/R non-Hodgkin lymphoma (NHL).

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT04045028 GO41036
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

General Inclusion Criteria (All Participants):

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy of >/= 12 weeks

Inclusion Criteria Specific to Arms A, C and E (R/R MM):

- Arm A only: Must have R/R MM for which no established therapy for MM is appropriate and available or be intolerant to those established therapies
- Arms C and E only: Participants with R/R MM who have received at least 3 prior lines of therapy.
- Measurable disease defined by laboratory test results.

Inclusion Criteria Specific to Arms B and D (R/R NHL):

- Participants with histologically confirmed B-cell NHL who have relapsed or failed to respond to at least two prior systemic treatment regimens and for which no suitable therapy of curative intent or higher priority exists.
- Must have at least one bi-dimensionally measurable lesion.

Exclusion Criteria:

General Exclusion Criteria (All Participants):

- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, monoclonal antibody, radioimmunoconjugate, antibody-drug conjugate, hormonal therapy, and/or radiotherapy, within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to initiation of study treatment
- Prior treatment with any anti-TIGIT agent
- Prior treatment with chimeric antigen receptor-T (CAR-T) therapy within 12 weeks before first study drug administration
- Autologous Stem-Cell Transplantation (ASCT) within 100 days prior to first study drug administration
- Active or history of autoimmune disease or immune deficiency
- Known active bacterial, viral (including SARS-CoV-2), fungal, mycobacterial, parasitic, or other infection at study enrollment, or any major episode of infection within 4 weeks prior to first study drug administration

Exclusion Criteria Specific to Arms A, C and E (R/R MM):

- Primary or secondary plasma cell leukemia
- Current or history of CNS involvement by MM

Exclusion Criteria Specific to Arms B and D (R/R NHL):

- Uncontrolled hypercalcemia or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
- Current or history of CNS lymphoma
- Current eligibility for ASCT

Other protocol defined inclusion/exclusion criteria could apply