ForPatients
by Roche

Cancer

A study exploring the safety and efficacy of Atezolizumab in combination with Obinutuzumab or Rituximab anti-CD20 therapy in participants with Relapse/Refractory Marginal Zone Lymphoma (MZL), Mantle Cell Lymphoma (MCL) and Waldenström Macrobulinemia (WM)

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	2016-003579-22 MO39107

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 II study exploring the safety and efficacy of atezolizumab administered in combination with obinutuzumab or rituximab anti-cd20 therapy in patients with relapsed/refractory mantle cell lymphoma, marginal zone lymphoma and waldenström macroglobulinemia

Trial Summary:

Atezolizumab + Rituximab in R/R MZL and Atezolizumab + Obinutuzumab in R/R MCL and WM

F. Hoffman La Roche (Switzerland)
Sponsor

Phase 2
Phase

2016-003579-22 MO39107
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male/Female	>= 18 years	No

This study is a multicenter, open-label, phase 2 study of atezolizumab (A) in combination with rituximab (R) or Obinituzumab (G), all administered by intravenous infusion (IV) in participants with refractory and/or relapsed Marginal Zone Lymphoma and Waldenström Macroglobulinemia or Mantle Cell Lymphoma. This study will evaluate the safety and

efficacy of the above combinations as well as pharmacokinetic parameters, biomarkers and occurrence of anti-drug antibodies of A, R and G.

Inclusion Criteria:

Histologically documented, CD20 positive non-Hodgkin lymphoma (NHL), relapsed or refractory MCL and MZL. For WM relapse/refractory intended as reappearance of monoclonal IgM protein and/or recurrence of bone marrow involvement, lymphadenopathy/ splenomegaly or symptoms attributable to active disease Patients must have failed at least 1 prior line of systemic treatment for mucosa associated lymphoid tissue patients.

- Bone marrow biopsy and/or other sites of disease at screening for tumor staging and response evaluation
- ECOG performance status of 0, 1 or 2
- Life expectancy>=12 weeks

Exclusion Criteria:

- Any approved anticancer therapy or hormonal therapy within 3 weeks prior to initiation of study treatment. Any radiotherapy within 4 weeks prior to initiation of study treatment.
- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days or 5 half-lifes prior to enrolment, whichever is longest.
- Known Central nervous system lymphoma, leptomeningeal lymphoma, or histologic evidence of transformation to a high-grade or diffuse large B-cell lymphoma
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures; patients with indwelling catheters are eligible
- Uncontrolled hypercalcemia or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
- History of other malignancy
- History of severe allergic or anaphylactic or other hypersensitivity reactions to chimeric or humanized or murine monoclonal antibodies or fusion proteins or murine proteins or known sensitivity or allergy to murine products