ForPatients
by Roche

Follicular LymphomaLymphoma

A Study Evaluating the Safety and Efficacy of Atezolizumab in Combination With Obinutuzumab Plus Lenalidomide in Patients With Relapsed or Refractory Follicular Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT02631577 2015-002467-42 BO29562

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/II Study Evaluating the Safety and Efficacy of Atezolizumab in Combination With Obinutuzumab Plus Lenalidomide in Patients With Relapsed or Refractory Follicular Lymphoma

Trial Summary:

This study will evaluate the safety, efficacy, pharmacokinetics and immunogenicity of induction treatment consisting of atezolizumab in combination with obinutuzumab plus lenalidomide in patients with relapsed or refractory follicular lymphoma (FL), followed by maintenance treatment with atezolizumab plus obinutzumab plus lenalidomide in patients who achieve a complete response (CR), a partial response (PR), or stable disease at end of induction.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

NCT02631577 2015-002467-42 BO29562
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2

- Relapsed or refractory FL after treatment with at least one prior chemoimmunotherapy regimen that included an anti-CD20 monoclonal antibody and for which no other more appropriate treatment option exists as determined by the investigator
- Histologically documented CD20-positive lymphoma as determined by the local laboratory
- Fluorodeoxyglucose-avid lymphoma (i.e., PET-positive lymphoma)
- At least one bi-dimensionally measurable lesion (>1.5 cm in its largest dimension by CT scan or magnetic resonance imaging [MRI])
- Availability of a representative tumor specimen and the corresponding pathology report for retrospective central confirmation of the diagnosis of FL
- Agreement to comply with all local requirements of the lenalidomide risk minimization plan
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use two adequate methods of contraception, including at least one method with a failure rate of <1% per year, for at least 28 days prior to Day 1 of Cycle 1, during the treatment period (including periods of treatment interruption), and for at least 18 months after the last dose of study treatment
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm for at least 3 months after the last dose of study treatment

Exclusion Criteria:

- Grade 3b follicular lymphoma
- History of transformation of indolent disease to diffuse large B-cell lymphoma (DLBCL)
- Known CD20-negative status at relapse or progression
- Central nervous system lymphoma or leptomeningeal infiltration
- Prior allogeneic stem-cell transplantation (SCT)
- Completion of autologous SCT within 100 days prior to Day (D) 1 of Cycle (C) 1
- Prior standard or investigational anti-cancer therapy as specified in protocol
- History of resistance to lenalidomide or response duration of <1 year
- Treatment with systemic immunosuppressive medications
- History of solid organ transplantation
- Clinically significant toxicity from prior therapy that has not resolved to Grade <=2 (according to the National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE], v4.0) prior to Day 1 of Cycle 1
- History of erythema multiforme, Grade >= 3 rash, or blistering following prior treatment with immunomodulatory derivatives such as thalidomide and lenalidomide
- Active bacterial, viral, fungal, or other infection
- Positive for hepatitis B surface antigen (HBsAg), total hepatitis B core antibody (HBcAb), or hepatitis C virus (HCV) antibody at screening
- Known history of HIV positive status
- History of progressive multifocal leukoencephalopathy
- History of autoimmune disease
- Contraindication to treatment for TE prophylaxis
- Grade <= 2 neuropathy
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of any significant, uncontrolled concomitant disease
- Inadequate hematologic function (unless due to underlying lymphoma)
- Abnormal laboratory values (unless due to underlying lymphoma)
- Pregnant or lactating or intending to become pregnant during the study