ForPatients
*by Roche*

Diffuse Large B-Cell Lymphoma (DLBCL)

# A Study of Atezolizumab in Combination With Either Obinutuzumab Plus Bendamustine or Obinutuzumab Plus (+) Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Participants With Follicular Lymphoma (FL) or Rituximab + CHOP in Participants With Diffuse Large B-Cell Lymphoma (DLBCL)

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 3 Countries | NCT02596971 2015-001364-19 BO29563 |

*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 Either Obinutuzumab Plus Bendamustine or Obinutuzumab Plus CHOP in Patients With Follicular Lymphoma or Rituximab Plus CHOP in Patients With Diffuse Large B-Cell Lymphoma

## *Trial Summary:*

This Phase Ib/II, open-label, multicenter, non-randomized study will evaluate the safety, efficacy, and pharmacokinetics of induction treatment consisting of atezolizumab in combination with either obinutuzumab + bendamustine (Atezo-G-benda) or obinutuzumab + CHOP (Atezo-G-CHOP) in participants with FL and atezolizumab + rituximab + chemotherapy (Atezo-R-CHOP) in participants with DLBCL, followed by post-induction treatment consisting of either atezolizumab plus obinutuzumab (Atezo-G) in participants with FL who achieve a complete response (CR) or partial response (PR) at end of induction (EOI) or atezolizumab alone in participants with DLBCL who achieve a CR at EOI.

| Hoffmann-La Roche | Phase 1/Phase 2 |
|---|---|
| Sponsor | Phase |

**NCT02596971 2015-001364-19 BO29563**
Trial Identifiers

## *Eligibility Criteria:*

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| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2
- For participants enrolled in the safety run-in phase: lymphoma classified as either relapsed or refractory FL after treatment with at least one prior chemoimmunotherapy regimen or previously untreated Grade 1, 2, or 3a FL that requires treatment
- For participants enrolled in the expansion phase: lymphoma classified as either previously untreated Grade 1, 2, or 3a FL that requires treatment or previously untreated advanced DLBCL
- Histologically documented cluster of differentiation 20 (CD20) positive lymphoma
- Fluorodeoxyglucose-avid lymphoma
- At least one bi-dimensionally measurable lesion (greater than [>] 1.5 centimeters in its largest dimension by CT scan or magnetic resonance imaging)
- Availability of a representative tumor specimen and the corresponding pathology report for retrospective central confirmation of the diagnosis of FL or DLBCL
- For women who are not postmenopausal or surgically sterile: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of less than [<] 1 percent [%] per year during the treatment period and for at least 18 months after the last dose of study treatment for participants in the Atezo-G-benda and Atezo-G-CHOP treatment groups or for at least 12 months after the last dose of study treatment for participants in the Atezo-R-CHOP treatment group
- For men: agreement to remain abstinent or use contraceptive measures and agreement to refrain from donating sperm

## *Exclusion Criteria:*

- Histological evidence of transformation of FL into high-grade B-cell non-Hodgkin's lymphoma (NHL)
- Central nervous system lymphoma or leptomeningeal infiltration
- For participants with DLBCL: preplanned consolidative radiotherapy
- Treatment with systemic immunosuppressive medications, including, but not limited to, prednisone, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents within 2 weeks prior to Day 1 of Cycle 1
- For participants with relapsed or refractory FL: prior allogeneic or autologous stem cell transplantation, anthracycline therapy, treatment with fludarabine or alemtuzumab within 12 months prior to Day 1 of Cycle 1, treatment with a monoclonal antibody, radioimmunoconjugate, or antibody-drug conjugate within 4 weeks prior to Day 1 of Cycle 1, radiotherapy, chemotherapy, hormonal therapy, or targeted small-molecule therapy within 2 weeks prior to Day 1 of Cycle 1
- History of solid organ transplantation
- History of severe allergic or anaphylactic reaction or known sensitivity to humanized or murine monoclonal antibodies
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab, obinutuzumab, rituximab, or bendamustine formulation, including mannitol
- Positive for hepatitis B surface antigen (HBsAg), total hepatitis B core antibody (HBcAb), or hepatitis C virus (HCV) antibody at screening
- History of progressive multifocal leukoencephalopathy
- Vaccination with a live virus vaccine within 28 days prior to Day 1 of Cycle 1

- History of other malignancy, autoimmune disease, or any significant, uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results
- Major surgical procedure other than for diagnosis within 28 days prior to Day 1 of Cycle 1, or anticipation of a major surgical procedure during the course of the study
- For participants who will be receiving CHOP: left ventricular ejection fraction (LVEF) <50% by multiple-gated acquisition (MUGA) scan or echocardiogram
- Inadequate hematologic, renal, and liver function (unless due to underlying lymphoma)