ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)Follicular LymphomaDiffuse Large B-Cell Lymphoma (DLBCL)

A Study of Obinutuzumab, Rituximab, Polatuzumab Vedotin, and Venetoclax in Relapsed or Refractory Follicular Lymphoma (FL) or Diffuse Large B-Cell Lymphoma (DLBCL)

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT02611323 2015-001998-40 GO29833

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 Obinutuzumab in Combination With Polatuzumab Vedotin and Venetoclax in Patients With Relapsed or Refractory Follicular Lymphoma and Rituximab in Combination With Polatuzumab Vedotin and Venetoclax in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Trial Summary:

This study will evaluate the safety, efficacy, and pharmacokinetics of induction treatment with obinutuzumab, polatuzumab vedotin, and venetoclax in participants with relapsed or refractory FL, and with rituximab, polatuzumab vedotin, and venetoclax in participants with DLBCL. Participants with FL who achieve complete response (CR), partial response (PR), or stable disease (SD) at the end of induction therapy will receive post-induction treatment with obinutuzumab and venetoclax, and participants with DLBCL who achieve CR or PR at the end of induction (EOI) will receive post-induction treatment with rituximab and venetoclax.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

NCT02611323 2015-001998-40 GO29833
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
- For obinutuzumab + polatuzumab vedotin + venetoclax treatment group, relapsed or refractory FL after treatment with at least one prior chemoimmunotherapy regimen that included an anti-cluster of differentiation 20 (CD20) (anti-CD20) monoclonal antibody (mAb) and for which no other more appropriate treatment option exists, as determined by the investigator
- For rituximab + polatuzumab vedotin + venetoclax treatment group, relapsed or refractory DLBCL after treatment with at least one prior chemoimmunotherapy regimen that included an anti-CD20 mAb and for which no curative option exists as determined by the investigator
- At least one bidimensionally measurable lesion

Exclusion Criteria:

- Known CD20-negative status at relapse or progression
- Prior allogeneic stem cell transplantation (SCT), or autologous SCT within 100 days prior to Day 1 of Cycle 1
- Grade 3b FL
- History of transformation of indolent disease to DLBCL
- Current use of systemic corticosteroids greater than (>) 20 mg prednisone per day (or equivalent); or prior anti-cancer therapy to include: radioimmunoconjugate within 12 weeks; mAb or antibody-drug conjugate within 4 weeks; or radiotherapy/chemotherapy/hormone therapy/targeted small-molecule therapy within 2 weeks prior to Day 1 of Cycle 1
- Central nervous system (CNS) disease
- Active infection
- Actual or potential cytochrome P450 (CYP) 3A interactions including: requirement for warfarin; use of strong and moderate CYP3A inhibitors or inducers within 7 days prior to first dose of venetoclax; or consumption of grapefruit, Seville oranges, or star fruit within 3 days prior to first dose of venetoclax
- Positive for human immunodeficiency virus (HIV) or hepatitis B or C
- Receipt of a live virus vaccine within 28 days prior to Day 1 of Cycle 1
- Poor hematologic, renal, or hepatic function
- Pregnant or lactating women
- Life expectancy <3 months