ForPatients
by Roche

Follicular LymphomaRelapsed or Refractory Follicular LymphomaDiffuse Large B-Cell Lymphoma (DLBCL)

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

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT02600897 2015-001999-22 GO29834

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 Lenalidomide in Patients With Relapsed or Refractory Follicular Lymphoma and Rituximab in Combination With Polatuzumab Vedotin and Lenalidomide 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 lenalidomide in participants with relapsed or refractory (R/R) follicular lymphoma (FL) and rituximab in combination with polatuzumab vedotin and lenalidomide in participants with R/R diffuse large B-cell lymphoma (DLBCL), followed by post-induction treatment with obinutuzumab in combination with lenalidomide in participants with FL who achieve a complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) and post-induction treatment with rituximab plus lenalidomide in participants with DLBCL who achieve a CR or PR at EOI.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT02600897 2015-001999-22 GO29834
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	# 18 Years	No

Inclusion Criteria:

- Age greater than or equal to (>/=) 18 years
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2
- For obinutuzumab in combination with polatuzumab vedotin and lenalidomide (G + Pola + Len) treatment group: R/R 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
- For rituximab in combination with polatuzumab vedotin and lenalidomide (R + Pola + Len) treatment group: R/R DLBCL after treatment with at least one prior chemoimmunotherapy regimen that included an anti-CD20 monoclonal antibody in patients who are not eligible for autologous stem-cell transplantation or who have experienced disease progression following treatment with high-dose chemotherapy plus autologous stem-cell transplantation
- Histologically documented CD20-positive B-cell lymphoma as determined by the local laboratory
- fluorodeoxyglucose (FDG)-avid lymphoma (i.e., positron emission tomography (PET)-positive lymphoma)
- At least one bi-dimensionally measurable lesion
- Agreement to remain abstinent or use adequate contraception, among women or men of childbearing potential

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 (CNS) lymphoma or leptomeningeal infiltration
- Prior allogeneic stem-cell transplantation (SCT), or autologous SCT within 100 days prior to Day 1 of Cycle 1
- Current use of systemic immunosuppressant(s), or prior anti-cancer therapy to include: lenalidomide, fludarabine, or alemtuzumab within 12 months; 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
- Active infection
- 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 less than (<) 3 months