ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)Lymphoma

A Study to Evaluate Glofitamab as Single Agent Administered After Pretreatment With Obinutuzumab in Chinese Patients With Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04657302 YO42610

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 I, Open-Label, Multicenter Study to Evaluate the Pharmacokinetics, Safety, Tolerability, and Efficacy of Glofitamab as Single Agent Administered After a Fixed, Single Dose Pretreatment of Obinutuzumab in Chinese Patients With Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Trial Summary:

This study will evaluate the pharmacokinetics, safety, tolerability, and efficacy of glofitamab as a single agent following a fixed single dose of obinutuzumab in Chinese patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who have failed two or more lines of systemic therapy.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT04657302 YO42610
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically-confirmed DLBCL

- Participants must have relapsed or failed to respond to at least two lines of prior systemic therapy (including at least one prior regimen containing anthracycline, and at least one containing an anti-CD20-directed therapy)
- Participants must have measurable disease: at least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension; or at least one bi-dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest dimension
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 1 or 1
- Adverse events from prior anti-cancer therapy must have resolved to Grade </=1
- Adequate liver, hematological, and renal function
- Negative serum pregnancy test within 7 days prior to study treatment in women of childbearing potential
- Women of childbearing potential must agree to remain abstinent (refrain from heterosexual intercourse) or use contraception as defined by the protocol, and agree to refrain from donating eggs during the treatment period and for at least 18 months after the final dose of obinutuzumab, 2 months after the final dose of glofitamab, and 3 months after the final dose of tocilizumab (if applicable)
- Men must agree to remain abstinent (refrain from heterosexual intercourse) or use contraception as defined by the protocol, and agree to refrain from donating sperm during the treatment period and for at least 3 months after the final dose of obinutuzumab, 4 months after the final dose of glofitamab, and 2 months after the final dose of tocilizumab (if applicable)
- Reside in the People's Republic of China

Exclusion Criteria:

- Richter's transformation
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment or any major episode of infection within 4 weeks prior to first study treatment
- Suspected or latent tuberculosis
- Positive for HIV, hepatitis C (HCV), or hepatitis B (HBV)
- Known or suspected chronic active Epstein-Barr virus infection
- Known or suspected history of hemaphagocytic lymphohistiocytosis (HLH)
- Prior treatment with systemic immunotherapeutic agents
- History of treatment-emergent immune-related adverse events associated with prior immunotherapeutic agents
- Documented refractoriness to an obinutuzumab monotherapy-containing regimen
- Treatment with standard radiotherapy, any chemotherapeutic agent, including CAR T therapy
- Prior solid organ or allogenic stem cell transplantation
- Autologous stem cell transplantation within 100 days prior to obinutuzumab infusion
- Active autoimmune disease requiring treatment
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapy (or recombinant antibody-related fusion proteins)
- History of confirmed progressive multifocal leukoencephalopathy (PML)
- Current or past history of CNS lymphoma
- Current or past history of central nervous system (CNS) disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results, including diabetes mellitus, history of relevant pulmonary disorders, and known autoimmune diseases
- Major surgery or significant traumatic injury < 28 days prior to obinutuzumab infusion (excluding biopsies) or anticipation of the need for major surgery during study treatment
- Another invasive malignancy in the last 2 years
- Significant cardiovascular disease

- Administration of a live, attenuated vaccine within 4 weeks before obinutizumab infusion, or anticipation that one will be required during the study
- Systemic immunosuppresive medications