ForPatients
by Roche

Lymphoma

A Study Evaluating the Safety and Efficacy of Glofitamab + Gemcitabine + Oxaliplatin in U.S. Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	2 Countries	NCT06624085 GO44900

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 Study Evaluating the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Glofitamab in Combination With Gemcitabine Plus Oxaliplatin in U.S. Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Trial Summary:

The purpose of the study is to evaluate glofitamab + gemcitabine + oxaliplatin in participants in the United States, including under-represented racial and ethnic populations, that have relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT06624085 GO44900
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically confirmed DLBCL, not otherwise specified (NOS)
- Relapsed (disease that has recurred following a response that lasted # 6 months after completion of the last line of therapy) or refractory (disease that did not respond to or that progressed < 6 months after completion of the last line of therapy) disease
- At least one prior line of systemic therapy

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- Participants who have failed only one prior line of therapy must not be a candidate for high-dose chemotherapy followed by autologous stem cell transplant (ASCT)
- At least one bi-dimensionally measurable (> 1.5 cm) nodal lesion, or one bi-dimensionally measurable (> 1 cm) extranodal lesion, as measured on CT scan
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2

Exclusion Criteria:

- Prior enrollment in Study GO41944 (STARGLO; NCT04408638)
- Participant has failed only one prior line of therapy and is a candidate for stem cell transplantation
- History of transformation of indolent disease to DLBCL
- High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements, and high-grade B-cell lymphoma NOS, as defined by 2016 WHO guidelines
- Primary mediastinal B-cell lymphoma
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products
- Prior treatment with glofitamab or other bispecific antibodies targeting both CD20 and CD3
- Prior treatment with gemcitabine or oxaliplatin
- Peripheral neuropathy or paresthesia assessed to be Grade >/= 2 according to NCI CTCAE v5.0 at enrollment
- Treatment with radiotherapy, chemotherapy, immunotherapy, immunosuppressive therapy, or any investigational agent for the purposes of treating cancer within 2 weeks prior to first study treatment
- Treatment with monoclonal antibodies for the purposes of treating cancer within 4 weeks prior to first study treatment
- Primary or secondary CNS lymphoma at the time of recruitment or history of CNS lymphoma
- Prior CNS involvement that has been definitively treated and confirmed via MRI or cerebrospinal fluid analysis to be in complete remission is permissible
- Current or history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- History of other primary malignancy, with exceptions defined by the protocol
- Significant or extensive cardiovascular disease, or significant pulmonary disease
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (exclusing fungal infections of nail beds) at study enrollment or any major episode of infection within 4 weeks prior to the first study treatment
- Documented severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection within 6 months of first study treatment, or positive SARS-CoV-2 test within 7 days prior to enrollment
- Suspected or latent tuberculosis
- Positive test results for hepatitis B (HBV) or hepatitis C (HCV)
- Known or suspected chronic active Epstein-Barr viral infection
- Known or suspected history of hemophagocytic lymphohistiocytosis (HLH)
- Known history of progressive multifocal leukoencephalopathy
- Prior solid organ transplantation
- Prior allogenic stem cell transplant
- Active autoimmune disease requiring treatment
- Prior treatment with systemic immunosuppressive medications within 4 weeks prior to first dose of study treatment
- Ongoing systemic corticosteroid use which, in the opinion of the investigator, puts the patient at increased risk of steroid-related iatrogenic adrenal insufficiency
- Recent major surgery (within 4 weeks before the first study treatment) other than for diagnosis
- Clinically significant history of cirrhotic liver disease

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