ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A Study Evaluating the Safety and Efficacy of RO7082859 or Mosunetuzumab (RO7030816) in Combination With Gemcitabine Plus Oxaliplatin in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma and High-Grade Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04313608 GO41943

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase Ib, Open-Label, Multicenter Study Evaluating the Safety and Efficacy of Glofitamab or Mosunetuzumab in Combination With Gemcitabine Plus Oxaliplatin in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma and High-Grade Large B-Cell Lymphoma

Trial Summary:

This study is designed to evaluate the safety and efficacy of glofitamab or mosunetuzumab in combination with gemcitabine and oxaliplatin (Glofit-GemOx or Mosun-GemOx) in participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBCL).

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

NCT04313608 GO41943
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

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- Histologically confirmed B-cell lymphoma, including one of the following diagnoses per the 2016 World Health Organization (WHO) classification of lymphoid neoplasms: DLBCL, not otherwise specified (NOS); HGBCL with MYC and BCL2 and/or BCL6 rearrangements; HGBCL, NOS
- R/R disease, defined as follows: Relapse: disease that has recurred following a response that lasted >/=6 months after completion of last line of therapy; Refractory: disease that progressed during therapy or progressed within 6 months (<6 months) of prior therapy
- At least one line of prior systemic therapy
- At least one bi-dimensionally measurable nodal lesion or one bi-dimensionally measurable extranodal lesion, as measured on positron emission tomography-computed tomography (PET/CT) scan
- Adequate hematologic function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs, as follows: Women must remain abstinent or use contraceptive methods with a failure rate of <1% per year during the treatment period and for at least 18 months after the final dose of obinutuzumab, 6 months after the final dose of gemcitabine, 9 months after the final dose of oxaliplatin, 3 months after the final dose of mosunetuzumab, 3 months after the final dose of tocilizumab, and 2 months after the final dose of glofitamab. Women must refrain from donating eggs during this same period
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating sperm, as follows: With a female partner of childbearing potential or pregnant female partners, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of <1% per year during the treatment period and for at least 2 months after the final dose of glofitamab, 2 months after the final dose of mosunetuzumab, 2 months after the final dose of tocilizumab (if applicable), 3 months after the final dose of obinutuzumab, and 6 months after the final dose of oxaliplatin or gemcitabine to avoid exposing the embryo. Men must refrain from donating sperm during this same period.

Exclusion Criteria:

- Participant has failed only one prior line of therapy and is a candidate for stem cell transplantation
- 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
- Contraindication to obinutuzumab, gemcitabine, oxaliplatin, or tocilizumab
- Prior treatment with a bispecific antibody targeting both CD20 and CD3, including glofitamab and mosunetuzumab
- Grade >1 peripheral neuropathy
- 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 the first study treatment
- Primary or secondary central nervous system (CNS) lymphoma at the time of recruitment or history of CNS lymphoma
- Current or history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results, including significant cardiovascular disease (such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the last 6 months, unstable arrhythmias, or unstable angina) or significant pulmonary disease (including obstructive pulmonary disease and history of bronchospasm)
- 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 (as evaluated by the investigator) within 4 weeks prior to first study treatment

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- Suspected or latent tuberculosis
- Positive test results for chronic hepatitis B virus (HBV) infection
- Positive test results for hepatitis C virus (HCV) antibody
- Known HIV-seropositive status
- Known or suspected chronic active Epstein-Barr virus infection
- Known or suspected history of hemophagocytic lymphohistiocytosis (HLH)
- History of progressive multifocal leukoencephalopathy
- Adverse events from prior anti-cancer therapy that have not resolved to Grade 1 or better (with the exception of alopecia and anorexia)
- Administration of a live, attenuated vaccine within 4 weeks prior to the first study treatment administration or anticipation that such a live, attenuated vaccine will be required during the study
- Prior solid organ transplantation
- Prior allogenic stem cell transplant
- Active autoimmune disease requiring treatment
- Prior treatment with systemic immunosuppressive medications (including, but not limited to, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents) within 4 weeks prior to the first dose of study treatment
- Corticosteroid therapy within 2 weeks prior to first dose of study treatment, with exceptions defined by the study protocol
- Recent major surgery (within 4 weeks before the first study treatment) other than for diagnosis
- Clinically significant history of liver disease, including cirrhosis

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