ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A clinical trial to examine the effectiveness and safety of glofitamab in combination with R-ICE (rituximab plus ifosfamide, carboplatin and etoposide) in people with relapsed or refractory (treatment-resistant) diffuse large B-cell lymphoma

A Study Evaluating the Efficacy, Safety, and Pharmacokinetics of Glofitamab in Combination With Rituximab Plus Ifosfamide, Carboplatin Etoposide Phosphate in Participants With Relapsed/Refractory Transplant Eligible Diffuse B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	NCT05364424 GO43693

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

The purpose of this study is to evaluate the preliminary efficacy, safety, and pharmacokinetics of glofitamab (glofit) in combination with rituximab plus ifosfamide, carboplatin, and etoposide (R-ICE) in participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who have failed one prior line of therapy incorporating an anti-cluster of differentiation (CD) 20 antibody (i.e., rituximab) and an anthracycline, and who are transplant or chimeric antigen receptor T-cell (CAR-T) therapy eligible, defined as being medically eligible for intensive platinum-based salvage therapy followed by autologous stem cell transplantation (ASCT) or for CAR-T therapy.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT05364424 GO43693
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

Why is the GO43693 clinical trial needed?

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Diffuse large B-cell lymphoma (DLBCL) is an aggressive type of cancer that can lead to death in less than a year if left untreated. The current ‘standard-of-care’ treatment for people with DLBCL when they are first diagnosed is called R-CHOP (rituximab, in combination with cyclophosphamide, doxorubicin, vincristine and prednisone). While around 60% of people can be cured by receiving R-CHOP, this therapy does not work in around 40% of people.

If a person with DLBCL does not respond to R-CHOP as a first-line therapy, but their physician believes they can tolerate more intensive therapy, they will receive further chemotherapy followed by an autologous stem cell transplant (ASCT). ASCT is where healthy stem cells, which form blood cells, are used to replace bone marrow (soft, sponge-like tissue in the centre of most bones) damaged by chemotherapy. However, if someone does not respond to this high-dose chemotherapy, they will not be eligible for ASCT. Because of this, there is a need for different high-dose chemotherapy regimens so that people with DLBCL (who are non-responsive to treatment or their cancer returns after receiving treatment) have a higher chance of responding well to treatment.

How does the GO43693 clinical trial work?

This clinical trial is recruiting people who have been diagnosed with diffuse large B-cell lymphoma (DLBCL). People can take part if they have relapsed (got worse after previous treatment) or refractory (did not respond to previous treatment) disease and are eligible for transplant.

The purpose of this clinical trial is to understand how well glofitamab works in combination with R-ICE (rituximab plus ifosfamide, carboplatin and etoposide) in people with relapsed or refractory transplant eligible DLBCL, as well as to test the safety of this treatment combination. This trial will also look at how the body responds to and processes the treatment combination.

Participants will be given glofitamab plus R-ICE for two to three months in 2–3 treatment cycles (depending on the clinic), each lasting 21 days. Following the screening visit, participants that join the study will be seen by the clinical trial doctor at the hospital five times in Cycle 1 and four times in Cycles 2 and 3. These hospital visits will include medical tests to see how the participant is responding to the treatment and any side effects they may be experiencing. Participants are free to stop taking the trial treatment and leave the clinical trial at any time.

After participants receive their last dose of glofitamab plus R-ICE, those who respond positively to the study treatment can receive ASCT. Those who do not receive ASCT for any reason will have an ‘end-of-treatment’ hospital visit. Participants will have follow-up

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appointments (by telephone or hospital visit) every 180 days for up to two years, either from the date of ASCT or from the ‘end-of-treatment’ visit.

What are the main endpoints of the GO43693 clinical trial?

The main clinical trial endpoint (the main result that is measured in the trial to see if the medicine has worked) is overall response rate (ORR), which is the percentage of participants who show a full or partial response to treatment within three cycles of glofitamab plus R-ICE.

The other clinical trial endpoints include:

- How well, how quickly and for how long a participant’s DLBCL responds to glofitamab plus R-ICE treatment
- How long before a participant's DLBCL gets worse
- How long a participant survives
- The number and seriousness of any side effects experienced by participants

Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old, have been diagnosed with relapsed or refractory DLBCL, have received previous treatment (which includes an anti-CD20 monoclonal antibody and an anthracycline) and are eligible for high-dose chemotherapy followed by ASCT.

People may not be able to take part in this trial if they have certain medical conditions or have previously received certain treatments, including ASCT. Women cannot take part in this trial if they are pregnant or breastfeeding, or are planning to become pregnant soon after the clinical trial.

What treatment will participants be given in this clinical trial?

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which clinical trial drugs are being used. Everyone who joins this clinical trial will be given glofitamab plus R-ICE for 2–3 cycles of 21 days.

In Cycle 1, participants will receive the following, given as intravenous (into the vein) infusions:

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- Obinutuzumab pre-treatment on Day 1
- Etoposide on Days 1–3
- Carboplatin, ifosfamide and mesna (a drug to protect the bladder from irritation) on Day 2
- Glofitamab on Days 8 and 15 (with increasing, ‘step-up’ doses)

In Cycles 2 and 3, participants will receive the following, given as intravenous infusions:

- Rituximab on Day 1
- Etoposide on Days 1–3
- Carboplatin, ifosfamide and mesna on Day 2
- Glofitamab on Day 8 (at the recommended dose)

During the first glofitamab dose in Cycle 1, participants will be required to stay in the hospital for 24 hours. Participants may be required to stay in hospital on subsequent visits of each cycle if it is considered necessary by the clinical trial doctor.

If a participant experiences a potential side effect called ‘cytokine release syndrome’ (CRS), they may receive another drug called tocilizumab.

Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the investigational drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Glofitamab and obinutuzumab

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Potential participants will be told about the known side effects of glofitamab and obinutuzumab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Glofitamab and obinutuzumab are given intravenously (an infusion into the vein) and participants will be told about any known side effects of intravenous administration.

Tocilizumab

Tocilizumab will only be given to participants if they experience a CRS event. Potential participants will be told about the known side effects of tocilizumab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Tocilizumab will be given intravenously (an infusion into the vein) and participants will be told about any known side effects of intravenous administration.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov

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