ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL) Lymphoma

A clinical trial to look at how well glofitamab plus R-CHOP (rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone) worked in people with ctDNA high-risk diffuse large B-cell lymphoma (DLBCL)

A Study to Evaluate the Safety and Efficacy of Glofitamab in Combination With Rituximab (R) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Circulating Tumor (ct)DNA High-Risk Patients With Untreated Diffuse Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	6 Countries	NCT04980222 GO43075

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

Trial Summary:

This Phase II, open-label, multicenter study will evaluate the safety, efficacy, and pharmacokinetics of glofitamab in combination with rituximab in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) in individuals with circulating tumor DNA (ctDNA) high-risk diffuse large B-cell lymphoma (DLBCL), as the first line of treatment.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04980222 GO43075
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the GO43075 clinical trial work? This clinical trial is recruiting people who have a type of disease called diffuse large B-cell lymphoma (DLBCL). In order to take part, patients must be “high-risk” by circulating tumour DNA (ctDNA) and should not have been previously treated for their DLBCL. ctDNA is DNA from your cancer that is freely circulating

in your blood. Being “high-risk” by ctDNA means that the levels of ctDNA in your blood did not sufficiently decrease after you started treatment.

The purpose of this clinical trial is to test the effects, good or bad, of glofitamab plus R-CHOP (rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone) in patients with DLBCL. In this clinical trial, you will only get glofitamab plus standard treatment with R-CHOP if your doctor finds that you are “high-risk” by ctDNA. If you want to take part in this clinical trial, you will have two cycles of standard treatment with R-CHOP (Cycles 1 and 2) and if you are found to be eligible for the clinical trial then you will start to also get glofitamab from Cycle 3.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must be at least 18 years old, have been diagnosed with DLBCL, be “high-risk” by ctDNA and not be limited in terms of activity or ability to take care of yourself.

You must not have been diagnosed with other types of lymphoma or have been treated for lymphoma in the past. If you have certain medical conditions or receive certain medications, you may not be able to take part in this clinical trial. If you are pregnant or breastfeeding, or are planning to become pregnant during or soon after the clinical trial, you will not be able to take part. Vaccination with live vaccines is not allowed within 28 days before starting the clinical trial (vaccines that are currently available for SARs-COV-2 [COVID-19] are not live).

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Before and after Cycle 1 of R-CHOP, the ctDNA levels in your blood will be tested. If your ctDNA levels do not sufficiently decrease after your first cycle of R-CHOP, your DLBCL will be classed as “high-risk” and you will continue in the clinical trial.

Everyone who continues in this clinical trial will be given:

- Glofitamab as an infusion (into the vein) on Day 8 and 15 in Cycle 3, Day 8 in Cycles 4–6 and Day 1 in Cycles 7–10, as well as R-CHOP as infusions (into the vein) on Day 1 of Cycles 3–6.
- Each cycle is 21 days in length.

Following your first glofitamab infusion during Cycle 3, you will stay in hospital for 48 hours so that clinical trial doctors can watch you closely for any side effects. You will also need to stay in hospital for 24 hours after your next two glofitamab infusions.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment glofitamab plus R-CHOP for four cycles (Cycles 3–6) and then glofitamab alone for four cycles (Cycles 7–10). You are free to stop this treatment at any time.

After being given treatment, you will be contacted by telephone or seen by the clinical trial doctor every 90 days (roughly three months). These appointments will include checks to see how you are responding to the treatment, and whether you have started any new treatments for your lymphoma.

What happens if I am unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

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

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