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Non Hodgkin Lymphoma (NHL) Diffuse Large B-Cell Lymphoma (DLBCL)

A study to understand the management of the cytokine release syndrome profile for glofitamab along with gemcitabine plus oxaliplatin in patients with relapsed/refractory aggressive B-cell non-Hodgkin's lymphoma

A Study to Evaluate the Optimization of the Cytokine Release Syndrome Profile for Glofitamab in Combination With Gemcitabine Plus Oxaliplatin in Participants With Relapsed/Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma

Trial Status
Recruiting

Trial Runs In
7 Countries

Trial Identifier
NCT06806033 2024-516791-15-00
GO45434

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

Trial Summary:

This Phase II trial evaluates the optimization of the cytokine release syndrome (CRS) profile for glofitamab in combination with gemcitabine and oxaliplatin (Glofit-GemOx) in participants with relapsed or refractory aggressive B-cell Non-Hodgkin's lymphoma. The study utilizes an optimized steroid premedication regimen and monitoring schedule specifically designed to enable the administration of the treatment regimen in an outpatient setting.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥18 Years

Healthy Volunteers
No

1. Why is this study needed?

Aggressive B-cell non-Hodgkin's lymphoma is a fast-growing type of blood cancer that affects the disease-fighting white blood cells (B-cell). It starts in the lymphatic system, a

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part of the body's defence system (immune system), and often spreads to other organs. Sometimes, aggressive B-cell non-Hodgkin's lymphoma may come back after initially responding to treatment (relapsed) or may not respond to the treatment at all (refractory). Therefore, there is always a need to find new treatments.

This study is testing a medicine called glofitamab in combination with 2 other cancer medicines called gemcitabine and oxaliplatin (referred to as GemOx). This combination is being developed as a treatment for relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma. In this study, the combination of glofitamab with GemOx (Glofit-GemOx) is considered experimental. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved this combination to treat relapsed or refractory DLBCL. Previous studies have shown that glofitamab can cause an unwanted effect called cytokine release syndrome (CRS). It occurs when the immune system reacts in an unusual way to an infection or cancer therapy. During this reaction, proteins called cytokines are released into the blood, causing symptoms like low blood pressure, rash, fever, chills, difficulty breathing, rapid heartbeat, nausea, and kidney damage.

This study aims to determine how often participants with relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma experience cytokine release syndrome after being treated with glofitamab in combination with GemOx.

2. Who can take part in the study?

People who are at least 18 years old with a diagnosis of relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma, such as diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBL), can take part in this study. People cannot take part in this study if they have other types of cancer, did not respond to only 1 prior treatment, and are suitable for a stem cell transplant. Stem cell transplant is a medical procedure in which a person's damaged cells are replaced with healthy, blood-forming cells. Women who are planning to get pregnant, are pregnant or are breastfeeding cannot participate in the study.

3. How does this study work?

People will be screened to check if they can participate in the study. The screening period will take place about 28 days before the start of treatment.

Everyone who joins this study will receive Glofit-GemOx as a drip into the vein (infusion) once every 3 weeks for 8 treatment cycles, followed by glofitamab alone for 4 treatment cycles. A treatment cycle is the period of treatment and recovery time before the next set of treatments is given. Participants will receive a single dose of obinutuzumab 7 days before the first dose of glofitamab to reduce the risk of CRS. Participants will also receive a steroid medicine to manage CRS in all the treatment cycles. They may also receive tocilizumab if the CRS event worsens.

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This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will meet the participants approximately 22 times over 40 weeks to check how well the treatment is working and any unwanted effects participants may have. Participants will have follow-up visits every 3 months after completing the study treatment, during which the study doctor will check on the participant's well-being. Total time of participation in the study will be about 5 years, depending on how the cancer responds to treatment. Participants have the right to stop study treatment and leave the study at any time if they wish to do so.

4. What are the main results measured in this study?

The main result of the study is to find out the number of participants with cytokine-release syndrome (CRS) and the severity of CRS in these participants.

Other key results that will be measured in the study include:

- Number of participants with serious CRS events
- Number of CRS events at start of glofitamab treatment in Cycle 1 compared to events in other cycles
- How CRS is managed and the outcome for participants who experience CRS event
- Number of participants with unwanted effects and the severity of unwanted effects
- Number of participants who are cancer-free or had at least a 30% decrease in the tumour size
- Time taken for the cancer to come back in a participant who was previously cancer free after undergoing treatment
- Time from the start of treatment until the first incidence of cancer worsening, or participants dying due to any cause

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future. It may not be fully known at the time of the study how safe and well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drugs Participants may have unwanted effects of the drugs used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have

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regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of glofitamab and obinutuzumab and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Glofitamab

Known unwanted effects include CRS event-related symptoms, a low number of neutrophils, which is a type of white blood cell that helps the body fight infections (neutropenia), vomiting, loose stools (diarrhea), difficulty in passing stools (constipation), and rash.

Obinutuzumab

Known unwanted effects include low numbers of neutrophils (neutropenia), decrease in red blood cells (anemia), difficulty passing stools (constipation), difficulty falling asleep (insomnia), infections, and cough.

Glofitamab and obinutuzumab, are given as a drip into a vein. Known unwanted effects with infusion include irritation where the injection is given, fever, chills, rash, redness, swelling, itching, or pain.

The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.