ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A clinical trial to test CC-220 or CC-99282 in combination with mosunetuzumab, and CC-99282 in combination with glofitamab, in people with B-cell non-Hodgkin lymphoma.

A Study Evaluating the Safety, Pharmacokinetics, and Efficacy of Mosunetuzumab or Glofitamab in Combination With CC-220 and/or CC-99282 in Participants With B-Cell Non-Hodgkin Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	5 Countries	NCT05169515 2023-505185-28-00 CO43805

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 study will evaluate the safety, efficacy, and pharmacokinetics of mosunetuzumab or glofitamab in combination with CELMoDs (CC-220 and/or CC-99282) in participants with B-cell NHL.

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

NCT05169515 2023-505185-28-00 CO43805
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the CO43805 clinical trial needed?

B-cell non-Hodgkin lymphoma (NHL) is a common type of cancer that affects a type of immune cell called B cells. Although there has been progress in treating NHL, many people who have NHL may not respond to treatment (their disease is refractory) or will experience a relapse (their disease returns). New drug combinations could help people with relapsed or refractory NHL to live longer.

This clinical trial aims to test the safety and effectiveness of CC-220 or CC-99282 when combined with mosunetuzumab, or CC-99282 when combined with glofitamab, and to understand how the body processes these treatment combinations.

2. How does the CO43805 clinical trial work?

This clinical trial is recruiting people who have a health condition called B-cell NHL. People can take part if they have relapsed or refractory NHL.

People who take part in this clinical trial (participants) will be given the clinical trial treatment CC-220 or CC-99282 in combination with mosunetuzumab (Group A) OR CC-99282 in combination with glofitamab (Group B) for up to 12 cycles of treatment. A treatment cycle is the period of treatment and recovery time before the next dose of treatment is given. Participants will be seen by the clinical trial doctor every week during the first two to three cycles, and then every 3 or 4 weeks in the remaining treatment cycles. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may be having. Participants' total time in the clinical trial will be up to roughly 3 years, as they will be seen for follow-up appointments every 3 months for 2 years after they have finished treatment. Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the CO43805 clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial to see if the drug has worked) are the type and number of dose-limiting toxicities (known as 'DLTs' - treatment side effects that are too severe to allow for an increase in the dose), and the number and seriousness of any other side effects.

Other clinical trial endpoints include:

- The number of participants who have no detectable cancer on scans (complete response rate)
- The number of participants with cancer that has shrunk or is not detectable on scans (overall response rate)
- The amount of time between cancer getting better to cancer progressing (duration of response)
- The amount of time between the start of treatment, to cancer first progressing, or a new treatment needed (progression-free and event-free survival)
- How long participants live (overall survival)

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and have NHL that either failed to respond or relapsed after treatment with at least one or two previous lines of systemic therapy (treatment that travels through the bloodstream) depending on which

treatment group they join. People may not be able to take part in this trial if they are pregnant or breastfeeding, have certain other medical conditions such as autoimmune, lung, liver or heart disease, or have previously received certain other treatments including mosunetuzumab, glofitamab or stem cell or organ transplant.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be put into groups depending on when they join and given either:

- **Group A**: Mosunetuzumab as an injection under the skin (subcutaneous) on Days 1, 8 and 15 of Cycle 1, then Day 1 of Cycles 2–12 and CC-220 as a capsule to be swallowed once a day on Days 1–21 of Cycles 2–12 OR CC-99282 as a capsule to be swallowed once a day on Days 1–14 of Cycles 2–12. Cycle 1 will last for 21 days and Cycles 2–12 will last for 28 days
- **Group B**: Glofitamab as an infusion into the vein on Days 8 and 15 of Cycle 1, then Day 1 of Cycles 2–12, and CC-99282 as a capsule to be swallowed once a day on Days 1–10 of Cycles 3–12. Each cycle will last for 21 days. People in this group will also need to have one pre-treatment dose of obinutuzumab as an infusion into the vein on Day 1 of Cycle 1

Participants may also receive tocilizumab as an infusion into the vein if they experience certain side effects during the clinical trial.

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

6. 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. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate 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. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Potential participants will be told about the known side effects of mosunetuzumab, glofitamab, obinutuzumab,

CC-220, CC-99282 and tocilizumab and, where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Mosunetuzumab will be given as a subcutaneous injection (inserting a needle into the fatty layer between the skin and muscle); glofitamab, obinutuzumab and tocilizumab are each given as an intravenous infusion (inserting a needle into a vein, usually in the arm); CC-220 and CC-99282 are each given as capsules (to be swallowed). Participants will be told about any known side effects of subcutaneous injections, intravenous infusions and swallowing capsules.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.