ForPatients
by Roche

Non Hodgkin Lymphoma (NHL) Follicular Lymphoma

A clinical trial to look at how safe and effective mosunetuzumab plus tiragolumab, with or without atezolizumab, is for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma (NHL)

An Open-Label, Multicenter Study Evaluating the Safety, Efficacy, and Pharmacokinetics of Mosunetuzumab in Combination With Tiragolumab With or Without Atezolizumab in Participants With B-Cell Non-Hodgkin Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Terminated	6 Countries	NCT05315713 CO43116

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 in combination with tiragolumab, with or without atezolizumab, in participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) who have received at least two previous lines of systemic therapy.

Hoffmann-La Roche Sponsor	**Phase 1/Phase 2** Phase

NCT05315713 CO43116
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the CO43116 clinical trial work?

This clinical trial is recruiting people who have a type of disease called B-cell non-Hodgkin lymphoma (NHL). In order to take part, patients must have ‘relapsed’ or ‘refractory’ B-cell NHL, which means that the cancer has come back after being treated or did not get better with at least two previous treatments.

The purpose of this clinical trial is to test the safety and effectiveness of mosunetuzumab plus tiragolumab, with or without atezolizumab, and to understand the way your body processes the combination.

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 and have been diagnosed with relapsed or refractory B-cell NHL.

You must not be pregnant or breastfeeding, or intending to become pregnant during the clinical trial or soon after. If you have received certain medications or have certain other medical conditions, you may not be able to take part in this clinical trial.

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?

The first part of the clinical trial (the safety run-in) aims to find the best dose of mosunetuzumab when combined with tiragolumab and atezolizumab. Depending on when you join the trial, you will be put into one of the following safety run-in treatment groups:

- Mosunetuzumab, given as an injection under the skin (subcutaneous) on Days 1, 8 and 15 of Cycle 1, and Day 1 of each cycle after that, and tiragolumab, given as an infusion into your vein on Day 1 of each cycle, for up to 17 three-week cycles
    - If a certain number of people have side effects with this treatment regimen, it may be adapted to start tiragolumab treatment later, at Day 1 of Cycle 2

- Mosunetuzumab, given as an injection under the skin (subcutaneous), tiragolumab given as an infusion into your vein, and atezolizumab, given as an infusion into your vein on Day 1 of each cycle, starting at Cycle 2, for up to 17 three-week cycles. The dose and timing of mosunetuzumab and tiragolumab in this group will be decided based on results from the previous treatment group

You will have at least eight cycles of clinical trial treatment, unless your disease gets worse before then. After eight cycles, your clinical trial doctor will run tests to check how well the treatment is working. If the treatment is working well, you will continue to be treated for up to 17 cycles in total, or until your disease gets worse (whichever occurs first).

This clinical trial is open-label, which means that both you and your clinical trial doctor will know which treatment you are receiving. Depending on the results from the safety run-in part of the clinical trial, more patients may be enrolled later (the expansion phase).

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

You will be given the clinical trial treatment (mosunetuzumab and tiragolumab, with or without atezolizumab) for up to 17 three-week cycles (roughly one year). You are free to stop this treatment at any time. After being given treatment for the first time, you will need to stay in hospital for 72 hours to check for any side effects. When you leave the hospital, you will still be seen regularly by the clinical trial doctor. Your clinical trial doctor will be able to give you more information on how often they will need to see you. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After you have finished treatment, your clinical trial doctor will follow up with you every three months (either by phone or clinic visit) for as long as you agree to it.

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: https://clinicaltrials.gov/ct2/show/NCT05315713

Trial-identifier: NCT05315713