

## Summary of Clinical Trial Results

This is a summary of the results of a clinical trial (called a 'study' in this document) – written for:

- members of the public and
- people who took part in the study.

This summary is based on information known at the time of writing.

The study started in May 2022 and finished in July 2023. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- **This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment**

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### Glossary

- Non-Hodgkin Lymphoma (NHL) = cancer of the lymph nodes.
- Diffuse Large B cell Lymphoma (DLBCL) / High-grade B cell lymphoma (HGBL) / transformed Follicular Lymphoma (trFL) = a fast-growing cancer of the lymph nodes
- Follicular Lymphoma (FL) = a slow-growing cancer of the lymph nodes
- Relapsed or refractory = the cancer has come back after being treated or did not get better with the previous treatment

## 1. General information about this study

### Why was this study done?

Non-Hodgkin's lymphoma (NHL) is a cancer of the lymph nodes. In this type of cancer, white blood cells grow abnormally and form tumours throughout the body.

Most NHL cases affect B-cells, which are a type of white blood cell. There are different types of NHL. Diffuse large B-cell lymphoma (DLBCL) is the most common type of NHL. High grade B-cell lymphoma (HGBL), transformed follicular lymphoma (trFL) and follicular lymphoma (FL) are other types of NHL.

People with NHL may be given several different types of treatment, including:

- Chemotherapy – medicines that kill cancer cells in the body
- Immunotherapy – medicines that help the body's immune system to attack tumours
- Bone marrow transplant (also called stem cell transplant)– a procedure where healthy stem cells that produce blood are infused into the body to replace unhealthy or damaged bone marrow stem cells.

There is a need for new treatment options for people with NHL. The people in this study had previously been given medicine for NHL, but this medicine did not work (refractory lymphoma), or the cancer came back after treatment (relapsed lymphoma).

This study looked at whether a medicine called mosunetuzumab in combination with tiragolumab is safe and worked for people with relapsed or refractory NHL. The study also planned to look whether mosunetuzumab in combination with tiragolumab and atezolizumab is safe and worked for people with relapsed or refractory NHL however this study arm never opened.

### What were the study medicines?

Mosunetuzumab and tiragolumab were the main medicines that were studied. The other medicine studied was tocilizumab.

**Mosunetuzumab** is one of the main medicines that was studied here.

- You say this as 'moe – sun – e – tooz – ue – mab'.
- It is a new type of immunotherapy molecule called a bispecific antibody. Antibodies are a type of blood protein normally made by the immune system to help defend the body against infection and cancer. Mosunetuzumab is called a bispecific antibody because it has two arms. One arm attaches to the surface of a type of white blood cell called B cells, including the cancer cells that cause NHL. The other arm recognises another type of white blood cell called T cells. T cells are important for the body's immune system and can help destroy cancer cells.
- By binding to both B cells and T cells, the medicine acts like a bridge to bring the T cells near the cancerous B cells. This encourages the T cells to destroy the cancer cells.
- Mosunetuzumab is an existing medicine given to people with relapsed or refractory follicular lymphoma.

**Tiragolumab** is a medicine that was studied here.

- You say this as ‘ti – rah – go – loo – mab’.
- It is a type of immunotherapy called a monoclonal antibody.
- The body’s immune system fights diseases like cancer, but sometimes cancer cells can block (stop) the immune system from attacking the cancer.
- Tiragolumab attaches to the surface of Natural Killer cells and T cells – these cells can destroy cancer cells. By attaching to these cells tiragolumab enhances their ability to attack and destroy cancer cells.

**Tocilizumab** is a medicine that was studied here.

- You say this as ‘toe – si – liz – oo – mab’
- It helps treat a possible side effect called cytokine release syndrome. Cytokine release syndrome can happen when the immune system reacts too strongly to medicines like mosunetuzumab.

## **What did researchers want to find out?**

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In this study, people were selected to receive 1 of 2 treatments. People in one group were treated with mosunetuzumab and tiragolumab.

People in the other group were to be treated with mosunetuzumab and tiragolumab and atezolizumab; however, no people received this treatment combination due to early study termination.

- Researchers did this study
  - to find out how safe mosunetuzumab was in combination with tiragolumab by checking how many people had side effects and seeing how serious the side effects were (see section 5 “What were the side effects?”).
- They also wanted to find out
  - how well mosunetuzumab worked in combination with tiragolumab (see section 4 “What were the results of the study?”).

### **The main questions that researchers wanted to answer were:**

What side effects did people with NHL have when treated with mosunetuzumab and tiragolumab?

### **Other questions that researchers wanted to answer included:**

How many people with NHL had smaller or no tumours after receiving treatment with mosunetuzumab and tiragolumab?

## **What kind of study was this?**

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This study was a ‘Phase 1b’ study, which means that this was one of the first studies for mosunetuzumab and tiragolumab for people with NHL. In this study, people with NHL took mosunetuzumab and tiragolumab to find out about the safety of mosunetuzumab and tiragolumab and to see if mosunetuzumab and tiragolumab worked to treat NHL.

This was an 'open label' study. This means that both the people taking part in the study and the study doctors knew what study drugs people were taking.

## When and where did the study take place?

The study started in May 2022 and finished in July 2023. This summary was written after the study had ended.

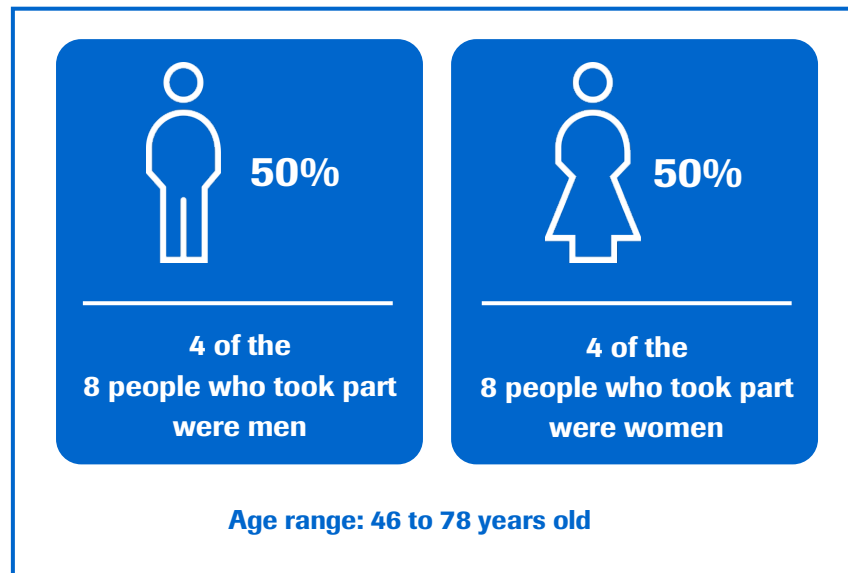
The study took place at 4 study centres across Australia, Belgium and USA.

USA  
Australia  
Belgium



## 2. Who took part in this study?

In this study, 8 people with NHL took part. 3 people had DLBCL, 3 had FL, 1 had HGBL and 1 had trFL. All people took mosunetuzumab and tiragolumab.



People could take part in the study if:

- They had NHL.
- They previously had at least one treatment of NHL, but the treatment did not work, or the cancer came back.
- There was no other treatment that was expected to work.

People could not take part in the study if:

- Their doctor thought they should have a stem cell transplant to treat the disease.
- They had previously taken any medicines that work in a similar way to mosunetuzumab or tiragolumab.
- They had previously taken mosunetuzumab or tiragolumab.
- They had lymphoma that had spread to the brain or spinal cord.

## 3. What happened during the study?

During the study, people were selected to get treated with mosunetuzumab and tiragolumab.



- 2 out of 8 people (25%) who received mosunetuzumab and tiragolumab had at least one **serious** side effect. The **serious** side effects and the number of people who had these **serious** side effects were:
  - 1 out of 8 people (13%) had
    - COVID-19 infection.
    - Aspiration pneumonia (when food or liquid is breathed into the airways of lungs, instead of being swallowed).
    - Diarrhea.
    - A fall and had to be hospitalized.
    - A severe illness in which the body is overwhelmed by infection (septic shock).
  - 1 out of 8 people (13%) had
    - Pain in their abdomen.
    - Cerebellar hematoma which is a type of hemorrhage inside the head.
  
- All patients (100%) had at least one side effect. The most common side effects – experienced by at least 1 in 5 (20%) of people – were:
  - 3 out of 8 people (38%) had low number of red blood cells (anaemia).
  - 3 out of 8 people (38%) had skin irritation caused by a reaction to the injection (injection site reaction).
  - 3 out of 8 people (38%) had shortness of breath (dyspnea).
  - 2 out of 8 people (25%) had a low number of a type of white blood cells (neutropenia).
  - 2 out of 8 people (25%) had asthenia.
  - 2 out of 8 people (25%) had nausea.
  - 2 out of 8 people (25%) had constipation.
  - 2 out of 8 people (25%) had decreased blood level of potassium (hypokalemia).
  - 2 out of 8 people (25%) had decreased blood level of phosphate (hypophosphatemia).
  - 2 out of 8 people (25%) had back pain.
  - 2 out of 8 people (25%) had osteoporosis.
  - 2 out of 8 people (25%) had COVID-19 infection.

**Question 2:** How many people with NHL had smaller or no tumours after receiving treatment with mosunetuzumab and tiragolumab?

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Another piece of information that researchers collected was how many people had smaller or no tumours during the study – compared to the start of the study.

- 5 out of 8 people (63%) had smaller or no tumours.
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This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see section 8).



## 5. What were the side effects from mosunetuzumab and tiragolumab?

Side effects are medical problems (such as feeling tired or having an infection) that happen during the study.

- This section describes side effects that the study doctor believed were **related to treatment with mosunetuzumab and tiragolumab**.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- It is important to be aware that the side effects reported here are from this single study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflets.
- Serious and common side effects are listed in the following sections.

### Serious side effects

A side effect is considered 'serious' if it is life-threatening, needs hospital care, or causes lasting problems.

None of the patients had any serious side effect, that the study doctor believed were related to the treatment with **mosunetuzumab and tiragolumab**.

### Most common side effects

During this study, 6 out of 8 people (75%) who received mosunetuzumab and tiragolumab had at least one side effect **from mosunetuzumab and tiragolumab**.

During this study, 4 out of 8 people (50%) had at least one side effect **from mosunetuzumab** only.

The most common side effects from mosunetuzumab and tiragolumab are shown in the following tables – these are the side effects experienced by at least 2 in 8 (25%) of patients. Some people had more than one side effect – this means that they are included in more than one row in the tables.

#### Group A

<b>Most common side effects reported in this study from mosunetuzumab and tiragolumab</b>	<b>People taking mosunetuzumab and tiragolumab (8 people total)</b>
Low number of red blood cells (anaemia)	25% (2 out of 8)
Low levels of a type of white blood cells (neutropenia)	25% (2 out of 8)
Shortness of breath (dyspnea)	25% (2 out of 8)

<b>Most common side effects reported in this study from <u>mosunetuzumab</u></b>	<b>People taking mosunetuzumab (8 people total)</b>
Injection site reaction	38% (3 out of 8)

### Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 8.

## 6. How has this study helped research?

The information presented here is from a single study of 8 people with NHL. These results helped researchers learn more about NHL and mosunetuzumab and tiragolumab.

This study looked at whether it was safe to give people with NHL mosunetuzumab and tiragolumab. It also looked at whether these medicines made the cancer smaller or go away altogether.

People in this study did not have side effects that the researchers were not expecting them to have. These side effects were noted in other studies for mosunetuzumab and tiragolumab where the same medicines had been taken as a single medicine.

It was difficult to determine how well mosunetuzumab and tiragolumab worked in this study since only a small number of people were treated with these medicines.

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- **This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.**

## 7. Are there plans for other studies?

Studies with mosunetuzumab and tiragolumab, alone or in combination with other medicines, are still happening, and further studies are planned.

## 8. Where can I find more information?

You can find more information about this study on the websites listed below:

- <https://classic.clinicaltrials.gov/ct2/show/NCT05315713>
- <https://forpatients.roche.com/en/trials/cancer/non-hodgkins-lymphoma/an-open-label--multicenter-study-evaluating-the-safety--95093.html>

## **Who can I contact if I have questions about this study?**

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If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – <https://forpatients.roche.com/en/trials/cancer/non-hodgkins-lymphoma/an-open-label--multicenter-study-evaluating-the-safety--95093.html>
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

## **Who organised and paid for this study?**

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This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland.

## **Full title of the study and other identifying information**

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The full title of this study is: "A PHASE IB/II OPEN-LABEL, MULTICENTER STUDY EVALUATING THE SAFETY, EFFICACY, AND PHARMACOKINETICS OF MOSUNETUZUMAB IN COMBINATION WITH TIRAGOLUMAB WITH OR WITHOUT ATEZOLIZUMAB IN PATIENTS WITH RELAPSED OR REFRACTORY B-CELL NON-HODGKIN LYMPHOMA".

- The protocol number for this study is: CO43116.
- The ClinicalTrials.gov identifier for this study is: NCT05315713.