ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A clinical trial to look at how safe, and how well mosunetuzumab alone or in combination with polatuzumab vedotin works in people with diffuse large B-cell lymphoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	6 Countries	NCT03677154 GO40554

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, pharmacokinetics, and preliminary efficacy of mosunetuzumab following first-line diffuse large B-cell lymphoma (DLBCL) immunochemotherapy in participants with a best response of stable disease or partial response, or in elderly/unfit participants with previously untreated DLBCL, or subcutaneous mosunetuzumab in combination with polatuzumab vedotin IV in elderly/unfit participants with previously untreated DLBCL.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT03677154 GO40554
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years	No

1. Why is the GO40554 clinical trial needed?

Diffuse large B-cell lymphoma (DLBCL) is the most common type of lymphoma. DLBCL affects a type of white blood cells called B lymphocytes (or B cells). Normally, B cells help protect the body from infection. In DLBCL, B cells become abnormal and collect in the lymph nodes and spleen. This causes lymph nodes to swell and form tumours. Standard treatment for DLBCL is a combination of chemotherapy and immunotherapy (known as ‘chemoimmunotherapy’). Immunotherapies are medicines that help the immune system find and destroy cancers. For some people their cancer does not respond to treatment

or it comes back after their first treatment. Some people are not well enough to be given chemotherapy. New drug combinations are needed against DLBCL.

Mosunetuzumab is an experimental drug, which means it has not been approved by health authorities for treating DLBCL. Mosunetuzumab is an antibody that attaches to CD20 – a protein found on some types of cancer cells. It also attaches to a protein called CD3 found on cancer-killing cells of the immune system. This pulls the cancer-killing cells closer to cancer cells, making them easier to destroy. Mosunetuzumab alone or in combination with a medicine called polatuzumab vedotin (which is used to treat DLBCL) may work well as a treatment for DLBCL. This clinical trial aims to test the safety of mosunetuzumab alone or in combination with polatuzumab vedotin at different doses, to see how well they work against DLBCL, and to understand how the body processes mosunetuzumab and polatuzumab vedotin.

2. How does the GO40554 clinical trial work?

This clinical trial is recruiting people with DLBCL. People who take part will be placed into a treatment group (A, B, or C). This will depend on their age, health, and prior DLBCL treatment. Group A will involve people who have had a treatment for their DLBCL that stopped their cancer from getting worse before. Group B and C will involve people who have not had treatment for their DLBCL, and who are elderly or not well enough to have full dose chemoimmunotherapy. People who take part in this clinical trial (participants) will be given the clinical trial treatment mosunetuzumab alone or with polatuzumab vedotin for around 6 months. Participants in Groups B and C may receive a further 6 months of clinical trial treatment. This depends on how well they respond to their first 6 months of treatment.

The clinical trial doctor will see them every week during the first 6 weeks, and then every 3 weeks while treatment is given. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. Participants will be seen for follow-up appointments about 1 month after their last dose of treatment then every 3–6 months for up to 2 years. Participants will stop clinical trial treatment if their cancer progresses or they start new treatment for DLBCL. The total time of participation in the clinical trial will be up to 2 and a half years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the GO40554 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see if the drug has worked) are:

- The number of participants whose cancer disappears (all groups) or shrinks (Group B and C) on scans
- The number and seriousness of side effects

- How the body breaks down and gets rid of mosunetuzumab and polatuzumab vedotin

The other clinical trial endpoints include:

- The amount of time a participant's cancer shrinks or disappears on scans before the cancer worsens
- The amount of time between the start of trial treatment and the progression of a participants' cancer getting worse
- How long participants live (all groups)
- The number of participants in Group B or C who have an improvement in physical ability after treatment (health-related quality of life) and the amount of time this lasts before physical ability, tiredness (fatigue), or DLBCL symptoms get worse
- How trial treatment affects the immune system

4. Who can take part in this clinical trial?

People with DLBCL can take part in **Group A** of this trial if they are at least 18 years old. Their lymphoma must have got better or stayed the same after chemoimmunotherapy treatment. People with untreated DLBCL can take part in **Groups B or C** if they are at least 80 years old, or aged between 65–79 years old and are not well enough to have full dose chemoimmunotherapy.

People may not be able to take part in this trial if they have DLBCL that affects the brain or spinal cord. Or, have other medical conditions like certain infections, another cancer type, autoimmune, lung, liver or heart disease. They cannot have had certain treatments before, including mosunetuzumab or a stem cell transplant. People in Group A may not be able to take part in this trial if they are pregnant or breastfeeding.

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

Everyone who joins this clinical trial will join 1 of 3 groups depending on the specific criteria for each group. Treatment will be given in 3-week (21-day) 'cycles'. A treatment cycle is the period of treatment and recovery time before the next dose of treatment is given.

- Group A: mosunetuzumab, given as an infusion (into the vein) every 3 weeks for 8 cycles
- Group B: mosunetuzumab, given as an infusion (into the vein) every 3 weeks for 8 cycles
- Group C: mosunetuzumab, given as an injection (under the skin) every 3 weeks for 8 cycles AND polatuzumab vedotin given as an infusion (into the vein) every 3 weeks for 6 cycles

Participants in Group B and C whose cancer shrinks or stays the same after 8 cycles may be given another 9 cycles of treatment. Group B participants whose cancer disappears after 8 cycles of treatment and then comes back may be given a further 8 cycles.

Participants may also receive tocilizumab as an infusion into the vein if they experience a certain side effect called ‘cytokine release syndrome’ 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. Participants will be told about the known side effects of mosunetuzumab, polatuzumab vedotin and tocilizumab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of infusions into the vein (intravenous infusions) or injections under the skin (subcutaneous injections).

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.