ForPatients
by Roche

Non-Hodgkin's Lymphoma Lymphoma Chronic Lymphocytic Leukemia

A clinical trial to look at how safe different doses of mosunetuzumab are to give with or without atezolizumab in people with B-cell non-Hodgkin's lymphoma or chronic lymphocytic leukaemia, how well they work, and how the body responds to and gets rid of the drugs

A Safety and Pharmacokinetic Study of BTCT4465A (Mosunetuzumab) as a Single Agent and Combined With Atezolizumab in Non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	7 Countries	NCT02500407 2023-506820-10-00 GO29781

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 is a Phase 1/2 dose-escalation study of BTCT4465A (Mosunetuzumab) administered as a single agent and in combination with atezolizumab in participants with relapsed or refractory B-cell NHL and CLL. The study will consist of a dose-escalation stage and an expansion stage where participants will be enrolled into indication-specific cohorts.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT02500407 2023-506820-10-00 GO29781
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years	No

1. Why is the GO29781 clinical trial needed?

B-cell non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL) are common types of cancers. They affect a type of immune cell called B cells. Many people with NHL and CLL may not respond to treatment (their disease is refractory) or their cancer comes back (relapses). New drug combinations could help people with relapsed or refractory

(R/R) B-cell NHL or CLL have better outcomes from treatment. Mosunetuzumab and atezolizumab are the experimental drugs in this clinical trial. Mosunetuzumab given on its own is approved by health authorities for the treatment of a certain type of R/R B-cell NHL called follicular lymphoma. Atezolizumab given on its own is approved by health authorities for the treatment of certain other cancers, but not B-cell NHL or CLL. Mosunetuzumab and atezolizumab have not been approved by health authorities for treating R/R B-cell NHL or CLL when given together. This clinical trial aims to test the safety and effectiveness of different doses of mosunetuzumab when given with or without atezolizumab in people with R/R B-cell NHL or CLL, and to understand how the body processes these drugs.

2. How does the GO29781 clinical trial work?

This clinical trial is recruiting people with R/R B-cell NHL or CLL. People who take part in this clinical trial (participants) will be given the clinical trial treatment mosunetuzumab with or without atezolizumab for up to
1 year unless their cancer worsens. Or they have unacceptable side effects, or they decide to leave the trial. Treatment will be given in 21-day cycles. A treatment cycle is the treatment and recovery time before the next dose is given. After 8 cycles of treatment (about 6 months), participants who have:

- No cancer on scans will stop receiving the clinical trial treatment and will continue to be monitored in the trial. If cancer comes back they may receive another 8 to 17 cycles of the same treatment
- Cancer present on scans will receive another 9 cycles of treatment over 6 months
- Been given mosunetuzumab on its own and their cancer has gotten worse, may be given mosunetuzumab combined with atezolizumab. Or they may stop receiving the clinical trial treatment

Participants may be required to stay in the hospital for 3 days after being given mosunetuzumab so that their health can be observed closely. The clinical trial doctor will see them at least once every week for up to
17 cycles. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. Participants will also be seen within 1 month of their last dose of treatment, then every 3 to 6 months for as long as they agree to it. Total time of participation in the clinical trial could be about 12 years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the GO29781 clinical trial?

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

- The maximum dose of mosunetuzumab on its own or combined with atezolizumab that can be given before unacceptable side effects occur
- The number of participants whose cancer disappears

- How the body processes mosunetuzumab with and without atezolizumab

The other clinical trial endpoints include:

- The number, type and seriousness of any side effects
- How mosunetuzumab and atezolizumab affect the immune system
- The number of participants whose cancer disappears or gets smaller and the amount of time this lasts if the cancer then gets worse
- The amount of time between the start of the trial and participants' cancer worsening
- How long participants live
- The change in the quality of life and symptoms of participants during versus the start of the trial

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged 18 years or over and have no other treatment options available for their R/R NHL or CLL. People may not be able to take part in this trial if they have certain types of lymphoma. Or have/had certain medical conditions such as active infections, stroke, heart, lung or autoimmune disease or other advanced cancers. People may not take part if they have received certain other treatments prior to or within a defined time period before treatment in this clinical trial. This includes organ transplant, transplant of stem cells that came from another person and specific cancer treatments. People who are pregnant or breastfeeding or are planning to become pregnant during or soon after the clinical trial also cannot take part.

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

Everyone who joins this clinical trial will be placed into a treatment group, depending on what groups are open to new participants and the clinical trial doctors' decision. Participants will be given either:

- **Group A:** Mosunetuzumab as an infusion (into the vein) every 3 weeks for up to 17 cycles
- **Group B:** Mosunetuzumab as an infusion (into the vein) on Days 1, 8 and 15 for the first 21-day cycle, then every 3 weeks from Cycle 2 for up to 17 cycles
- **Group D:** Mosunetuzumab as an injection under the skin every 3 weeks for up to 17 cycles
- **Group E:** Mosunetuzumab as an infusion (into the vein) on Days 1, 8 and 15 for the first 21-day cycle, then mosunetuzumab and atezolizumab, each given as an infusion (into the vein) every 3 weeks from Cycle 2 for up to 17 cycles
- **Group F:** Mosunetuzumab as an injection under the skin on Days 1, 8 and 15 for the first 21-day cycle, then every 3 weeks for up to 17 cycles

Participants may also receive tocilizumab as an infusion (into the vein) if they experience a side effect called 'cytokine release syndrome' due to an over-reaction of the immune system to clinical trial treatment. 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, atezolizumab, 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) and 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.