ForPatients
by Roche

Multiple Myeloma

A clinical trial to look at the safety and early activity of cevostamab when given subcutaneously at different doses in people with multiple myeloma after other treatments have not worked

An open-label, multicenter, phase Ib trial evaluating the safety, pharmacokinetics and activity of subcutaneous cevostamab (BFCR4350A) in patients with relapsed or refractory multiple myeloma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	5 Countries	ISRCTN26168155 GO43227

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

The purpose of this study is to evaluate the safety and tolerability of subcutaneous (SC) cevostamab, including estimation of the maximum tolerated dose (MTD), characterization of dose-limiting toxicity (DLTs), and to identify the recommended phase II dose (RP2D) of SC cevostamab in participants with relapsed or refractory multiple myeloma (R/R MM)

F. Hoffmann-La Roche (Switzerland)
Sponsor

ISRCTN26168155 GO43227
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	>=18 years	No

The aim of this document is to give people interested in this trial the background, treatment plan, scope of participants who are able to take part, benefits and risks. We recommend that this should be read carefully by potential participants and shared with close family members and caregivers.

1. Why is the clinical trial needed?

Multiple myeloma (MM) is a type of bone marrow cancer. In cases where a person's cancer comes back after treatment (relapsed MM) or does not respond to treatment (refractory MM), other treatment options are needed. Researchers hope that using drugs like cevostamab, designed to help a person's own immune system target and destroy cancer cells, will provide better health outcomes for people living with relapsed or refractory MM.

Hover over glossary definition for bone marrow: A soft, spongy tissue that is found in the center of most bones and is where most blood cells are made.

2. How does the clinical trial work?

This clinical trial is recruiting people who have been diagnosed with relapsed or refractory MM.

The purpose of the trial is to test the safety of cevostamab, delivered as an injection into the layer between the skin and the muscle (subcutaneously) at different doses, and to understand the way the body responds and processes cevostamab. This trial will also look at how well cevostamab is tolerated and how active it is in RR MM. These results will then be used to help doctors decide which dose to give to people living with relapsed or refractory MM in future clinical trials.

Participants will be given cevostamab, the clinical trial treatment, for up to one year. Participants will have a follow-up visit approximately one month after receiving their last dose of cevostamab, or before starting a new anti-cancer treatment. Thereafter, participants will continue to be followed by telephone call, review of medical records and/or clinic visits approximately every 3 months until study termination or withdrawal from follow-up, whichever happens first.

The trial is split up into 13 periods called "cycles", each lasting 28 days. In Cycle 1 (at a minimum), participants will need to stay in hospital for at least three days (72 hours) after each of the three injections of cevostamab to be monitored for side effects. Participants will then be seen by the clinical trial doctor every two weeks during Cycles 2–6, and then every four weeks during Cycles 7–13. Participants that meet certain criteria may be eligible for receiving additional cycles of cevostamab treatment.

The hospital visits will include giving cevostamab injections, medical tests to see how the participant is responding to the treatment and any side effects they may be experiencing.

Participants are free to stop taking the trial treatment and leave the clinical trial at any time.

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

The main clinical trial endpoints (the main results that are measured in the trial to see if the medicine is safe and has worked) are: the number and seriousness of any side effects experienced by the participant while taking the trial treatment, and the relationship between cevostamab dose and its safety profile.

Other clinical trial endpoints include:

- How well, how quickly and for how long a participant's MM responds to cevostamab treatment;
- How long before a participant's MM cancer gets worse;
- How long a participant survives; and
- How the levels of cevostamab in the blood affect the body and how the immune system responds to cevostamab.

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old, have been diagnosed with relapsed or refractory MM, and if they have no alternative treatment options.

People may not be able to take part in this trial if they have previously received certain cancer treatments, are pregnant or breastfeeding, or are planning to become pregnant, or have a history of autoimmune disease, severe allergies or certain other medical conditions.

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

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which medicine is being used to treat each participant. Everyone who joins this clinical trial will be given cevostamab as a subcutaneous injection for up to 13 cycles:

- In Cycle 1, all participants will receive step up (increasing) doses of cevostamab on Day 1, Day 8, and Day 15 (target dose reached on Day 15)
- In Cycles 2–6, participants will receive the target dose of cevostamab every two weeks
- In Cycles 7–13, participants will receive the target dose of cevostamab every four weeks

In the dose escalation part of the study, increasing doses of cevostamab will be tested on groups of participants to see if they are safe and effective. Once a safe dose/s are established, more participant groups will be treated with those safe doses to collect more data to establish their safety and effectiveness, in the dose expansion part of the study. Each participant will be enrolled in either dose escalation or dose expansion and will be assigned to a specific dosing group, also known as a cohort.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the trial treatment or its use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants 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. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Cevostamab

Potential participants will be told about the known side effects of cevostamab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Cevostamab will be given by subcutaneous injection (involves inserting a short needle into the tissue layer between the skin and the muscle of, for example, the abdomen or upper thigh). Participants will be told about any known side effects of subcutaneous injection.

If a participant experiences a potential side effect called ‘cytokine release syndrome’ (when the body’s immune cells are activated and release large amounts of inflammatory substances throughout the body), they may receive another medicine called tocilizumab.

Tocilizumab

Potential participants will be told about the known side effects of tocilizumab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Tocilizumab will be given by intravenous infusion (involves inserting a needle into a vein to allow the medicine to enter the bloodstream right away). Participants will be told about any known side effects of intravenous infusions.

Potential benefits associated with the clinical trial

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A participant's health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **ForExpert** tab on the specific ForPatients page or follow this link to the ISRCTN registry: https://www.isrctn.com/ISRCTN26168155.