ForPatients
by Roche

Multiple Myeloma

A clinical trial to look at how safe and well cevostamab works in people with multiple myeloma after other treatments have not worked

A Study Evaluating the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen (BCMA)-Exposed Participants With Relapsed/Refractory Multiple Myeloma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	8 Countries	NCT05535244 2021-006816-10 CO43476

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 efficacy, safety, and pharmacokinetics of cevostamab in participants with relapsed or refractory multiple myeloma (R/R MM) via intravenous (IV) infusion.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT05535244 2021-006816-10 CO43476
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the CAMMA 2 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. Cevostamab is a type of drug called a T-cell dependent bispecific antibody. It works by binding to certain proteins on myeloma cells and cells of the immune system to bring them closer together to help the immune system destroy the myeloma cells. Drugs like cevostamab, called immunotherapies, help a person's own immune system target and destroy cancer cells. Researchers hope that immunotherapies will provide better health outcomes for people with relapsed or refractory MM. This clinical trial aims to find out the effects, good or bad, of cevostamab and to

understand the way the body responds to and processes cevostamab in people with relapsed or refractory MM.

2. How does the CAMMA 2 clinical trial work?

This clinical trial is recruiting people with relapsed or refractory MM. People who take part in this clinical trial (participants) will be given the clinical trial treatment cevostamab for as long as it can help them or until they are unable to tolerate the treatment due to side effects (unexpected medical problems). Participants will stay in the hospital for observation for at least 48 hours after the first three doses of cevostamab, with the first two doses given 1–3 days apart (depending on how they tolerate the treatment) in a single visit. Future doses may be given on an outpatient basis and the clinical trial doctor will see them every 3 weeks. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. If cevostamab treatment is stopped due to MM getting worse, an end of treatment visit will take place 30 days after the last dose, and the clinical trial doctor will follow up with participants approximately every 3 months until the end of the clinical trial for as long as they agree to it. If cevostamab treatment is stopped for any other reason, the clinical trial doctor will follow-up with participants approximately every month for as long as they agree to it and until MM gets worse, they start a new treatment for MM, or the clinical trial ends. The total time of participation in the clinical trial will depend on how their MM responds to treatment. This could range from 1 day to more than 4 years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the CAMMA 2 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see if the drug has worked) are how many participants' cancer shows a positive response to treatment and how good this response is (objective response rate), and the number and seriousness of any side effects that occur while on treatment.

The other clinical trial endpoints include:

- The amount of time between cancer getting better from treatment and then getting worse (duration of response)
- The number of people with no signs of cancer on scans or tests (complete response rate)
- The number of people with at least a 90% improvement in their disease (very good partial response)
- The amount of time between the start of the trial to cancer first getting better, and to the best response to treatment
- The number of people with no disease detected after treatment
- How long people live (overall survival)
- How long people live without their cancer worsening (progression-free survival)

- Levels of cevostamab in the blood at different time points
- Number of people with less tiredness and better quality of life

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 have previously received treatment with certain cancer immunotherapies that target a part of myeloma cells called BCMA (including CAR-T, antibody-drug conjugate, and T-cell dependent bispecific antibody therapies). People may not be able to take part in this trial if they have received previous treatment with cevostamab or certain other treatments, have certain other medical conditions, are pregnant or breastfeeding, or are planning to become pregnant during or shortly after the trial.

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

Everyone who joins this clinical trial will be given cevostamab as an intravenous infusion (into the vein). The clinical trial is split up into periods called ‘cycles’, each lasting 21 days:

- In Cycle 1, participants will receive step-up (or increasing) doses of cevostamab on Day 1, Days 2#4, and Day 8 (target dose reached on Day 8)
- From Cycle 2, participants will receive cevostamab once every 21 days at the target dose

Step-up dosing aims to prevent and/or reduce side effects. If a participant experiences a potential side effect called ‘cytokine release syndrome’ (when the body’s immune cells release large amounts of inflammatory substances throughout the body), they may receive another drug called tocilizumab. 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 drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug 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. Cevostamab and tocilizumab will be given by intravenous infusion (into a vein). Participants will be told about any known side effects of intravenous infusions.

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.