ForPatients
by Roche

Multiple Myeloma

A clinical trial to look at the safety of cevostamab alone and in combination with other treatments in people with relapsed or refractory multiple myeloma

A Study Evaluating the Safety, Pharmacokinetics, and Activity of Cevostamab in Participants With Relapsed or Refractory Multiple Myeloma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	NCT04910568 2021-000238-33 GO42552

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 Phase Ib, multicenter, open-label study will evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of cevostamab monotherapy, cevostamab plus pomalidomide and dexamethasone (Pd) or cevostamab plus daratumumab and dexamethasone (Dd) which will be administered to participants with relapsed or refractory multiple myeloma (R/R MM) via intravenous (IV) infusion.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT04910568 2021-000238-33 GO42552
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. How does the CAMMA 1 clinical trial work?

This clinical trial is recruiting people who have a type of disease called multiple myeloma. In order to take part, participants must have relapsed disease (multiple myeloma that has become active again after effective treatment) or refractory disease (multiple myeloma that has not responded to treatment or has become resistant to it).

The purpose of this clinical trial is to understand how well cevostamab works and how safe it is when used alone or in combination with other drugs, such as pomalidomide and dexamethasone, or daratumumab and dexamethasone, to treat multiple myeloma.

2. How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with relapsed or refractory multiple myeloma. To receive cevostamab alone, participants should have no available, tolerable, or appropriate therapies (Group A); in order to receive cevostamab in combination with other multiple myeloma drugs, participants should have received previous treatment with certain multiple myeloma drugs including a proteasome inhibitor and an immunomodulatory drug (Group B and Group C).

You must not have already been treated with cevostamab or a similar drug. If you have previously received certain other medications or have other medical conditions that could interfere with the clinical trial, you may not be able to take part. You must not be pregnant or breastfeeding or intending to become pregnant during or shortly after the clinical trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or use appropriate contraception for safety reasons.

3. What treatment will I be given if I join this clinical trial?

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which clinical trial drugs are being used. Everyone who joins this clinical trial will be enrolled into one of three treatment groups depending on what treatments they have previously received. Treatments will be given regularly in ‘cycles’ - a treatment cycle is the treatment and recovery time before the next dose of treatment is given.

- **Group A**
    - Cevostamab, as an infusion into the vein. Cevostamab will be given at different intervals throughout the treatment period (weekly, then every 2 weeks, and then every month).
- **Group B**
    - Cevostamab, as an infusion into the vein. Cevostamab will be given as a pre-phase treatment on days 1, 8, and 15 before Cycle 1. Cevostamab will then be given on days 1 and 15 during cycles 1#6 and then every 4 weeks from Cycle 7 onwards
    - Pomalidomide, as a capsule to be swallowed every day from Cycle 1 on days 1# 21 of each 28-day cycle
    - Dexamethasone, as an infusion into the vein on days 1, 8 and 15 during pre-phase, and days 1 and 15 during Cycle 1 as a pre-medication prior to cevostamab treatment. In Cycle 1, dexamethasone will also be given as an oral tablet on days 8 and 22. Dexamethasone will then be given as an oral tablet on days 1, 8, 15, and 22 of cycles 2#4. The clinical trial doctor may decide that there is no need to give dexamethasone after Cycle 4.
- **Group C**
    - Cevostamab, as an infusion into the vein. Cevostamab will be given on days 2, 9 and 16 during Cycle 1, then every 3 weeks during cycles 2#8, and every 4 weeks from Cycle 9 onwards
    - Daratumumab, as a subcutaneous (under the skin) injection. Daratumumab will be given on days 1, 8, and 15 during cycles 1#3, then every 3 weeks during cycles 4#8, and every 4 weeks from Cycle 9 onwards
    - Dexamethasone, as an infusion into the vein on days 2, 9 and 16 during Cycle 1 and on day 1 of Cycle 2, as a pre-medication prior to cevostamab treatment. Dexamethasone may also be given as either oral tablet or as an infusion into the vein on days 1, 8 and 15 in Cycle 1, days 8 and 15 in Cycle 2 and on Day 1 in cycles 3–4. The clinical trial doctor may decide that there is no need to give dexamethasone after Cycle 4.

During this time, the clinical trial doctor will see participants regularly, at least every 1#2 weeks and then on Day 1 of later cycles. Some participants may also be treated with a drug called tocilizumab if they experience specific side effects related to inflammation.

4. How often will I be seen in follow-up appointments and for how long?

Participants in Group A will be given the clinical trial treatment cevostamab for a maximum of 13 cycles. Some participants may be eligible for additional cycles of cevostamab treatment (known as re-treatment) if they meet certain criteria.

Participants in Groups B and C will be given cevostamab together with either pomalidomide/dexamethasone or daratumumab/dexamethasone. You may continue to

receive treatment until your disease worsens or until you experience unmanageable side effects due to the clinical trial treatment (dexamethasone may be stopped earlier). You are free to stop the clinical trial treatment at any time. After stopping treatment, you will still be seen regularly by the clinical trial doctor roughly every 3 months. These hospital visits will include physical check-ups and blood tests to see how you have responded to treatment.

5. What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular medical care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

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