

ForPatients

by Roche

Multiple Myeloma

Cevostamab in combination with pomalidomide and dexamethasone versus standard of care in patients with previously treated multiple myeloma

A Phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of cevostamab in combination with pomalidomide and dexamethasone versus standard of care in patients with multiple myeloma who have received one to three prior lines of therapy

Trial Status
Recruiting

Trial Runs In
2 Countries

Trial Identifier
NCT07555938 2025-524028-23-00
CO46096

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Cevostamab in Combination With Pomalidomide and Dexamethasone Versus Standard of Care in Patients With Multiple Myeloma Who Have Received One to Three Prior Lines of Therapy

Trial Summary:

The purpose of this study is to assess the efficacy and safety of cevostamab in combination with pomalidomide and dexamethasone (CevosPd) versus standard of care (SOC) in participants with multiple myeloma (MM) who have received one to three prior lines of therapy and have been exposed to an anti-CD38 monoclonal antibody (mAb) and lenalidomide.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT07555938 2025-524028-23-00 CO46096
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

ForPatients

by Roche

1. Why is this study needed?

Multiple myeloma (MM) is a type of cancer that affects plasma cells in the bone marrow. Plasma cells are a type of white blood cell that helps fight infection. In multiple myeloma, these plasma cells become cancerous. They multiply rapidly and crowd out healthy cells in the bone marrow. Different types of medicines are given as standard treatment depending on the type of MM a person has. But for most people, MM eventually comes back after treatment or does not respond to treatment (known as 'relapsed/refractory' or 'R/R' MM). 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.

This study is testing a medicine called cevostamab. It is being developed to treat R/R MM.

Cevostamab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved cevostamab in combination with pomalidomide and dexamethasone for the treatment of multiple myeloma.

This study aims to compare the effects of cevostamab in combination with pomalidomide and dexamethasone against standard of care in people with multiple myeloma.

2. Who can take part in the study?

People (males and females) of at least 18 years of age with MM can take part in the study if they have been diagnosed with R/R MM and have been given 1 to 3 previous treatments for MM.

People may not be able to take part in this study if they have previously received certain cancer treatments, have an autoimmune disease, or have certain other medical conditions. People who are pregnant, planning to become pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 28 days before the start of treatment.

Everyone who joins this study will be split into 2 groups randomly (like flipping a coin) and given either:

- Cevostamab, given as a drip into the vein (intravenous infusion), 4 times for the first 3 weeks, then twice a month, and reduced to once a month thereafter, along with

ForPatients

by Roche

dexamethasone (as a drip or a pill). After the first few weeks, pomalidomide, given as a pill, for 3 weeks every 4 weeks. OR

- One of 3 standard treatments (daratumumab, elotuzumab, or carfilzomib), chosen by the study doctor. Daratumumab will be given as injection under the skin, and elotuzumab, or carfilzomib given as a drip into the vein. Daratumumab and elotuzumab will be given with pomalidomide (a pill) and dexamethasone (a pill or drip), while carfilzomib will be given with dexamethasone (a pill).

Participants will have an equal chance of being placed in either group.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants twice every week for the first 3 weeks, then every 2 weeks, and then once a month after that. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have to stay overnight in the hospital on at least one visit. Participants will have follow-up visits every 1 to 3 months after completing the study treatment, during which the study doctor will check on the participant's well being. Total time of participation in the study will be about 1 day to more than 3 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are the number of participants who do not have cancer on tests or scans (including tests where a small sample of bone marrow is taken from inside a bone using a needle) after 9 months of treatment. The study also measures how long participants live without their cancer getting worse. Other key results measured in the study include:

- How long participants live and how many participants have significant improvement in the condition being treated
- How participants health affects their daily life and well-being
- How well cevostamab treatment combination works against MM
- The number and seriousness of unwanted effects
- How the immune system responds to cevostamab treatment combinations.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural

ForPatients

by Roche

progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicines Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Cevostamab Participants will be told about the known unwanted effects of cevostamab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include an unusual immune system reaction to cancer immunotherapy (cytokine release syndrome). If a participant experiences a potential unwanted effect called 'cytokine release syndrome', they may receive another medicine called tocilizumab as a drip into a vein.

Cevostamab will be given as a drip into the vein. Known unwanted effects of infusion include fever and chills, skin rash, swelling, nausea, vomiting, headache, cold-like symptoms, difficulty breathing, and low blood pressure.

Pomalidomide and Dexamethasone Participants will be told about the known unwanted effects of pomalidomide and dexamethasone, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include decreased red and white blood cells, bone pain, feeling less hungry than usual, cough, difficulty breathing, tiredness, swelling of the arms or legs, muscle cramps and fever.

The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 at screening and immediately prior to start of administration of study treatment.
- Individuals with ECOG Performance Status of 2 solely due to local symptoms of myeloma (e.g., pain) are eligible
- MM diagnosis according to the International Myeloma Working Group (IMWG) diagnostic criteria
- Received one to three lines of prior therapy that included at least two consecutive cycles of either of the following: A regimen containing an anti-CD38 therapy, a regimen containing lenalidomide
- Participants must have measurable disease during screening

Exclusion Criteria:

ForPatients

by Roche

- Known history of amyloidosis (e.g., positive Congo Red stain or equivalent in tissue biopsy or documented within serum amyloid P component scan)
- Plasma cell leukemia or circulating plasma cell count exceeding 500 cells/liter (L) or 5% of the peripheral blood white cells
- GI disease that might significantly alter absorption of oral drugs
- Participants must not have any ongoing CNS disease or non-secretory myeloma