ForPatients
by Roche

Multiple Myeloma

A clinical trial to look at how safe forimtamig is at different doses, how the body processes it, and how well it works against multiple myeloma that has come back after previous treatment

A Study Evaluating the Safety and Pharmacokinetics of Escalating Doses of Forimtamig in Participants With Relapsed or Refractory Multiple Myeloma (r/r MM)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	8 Countries	NCT04557150 2023-504571-25-00 BP42233

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 first-in-human, open-label, uncontrolled, multi-center, monotherapy, dose-escalation and dose expansion study. Forimtamig will be administered to participants with r/r MM for whom no standard-of-care treatment exists or who are intolerant to those established therapies. The study consists of two parts: dose-escalation of forimtamig (Part 1) and a randomized dose expansion of forimtamig (Part 2).

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT04557150 2023-504571-25-00 BP42233
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the BP42233 clinical trial needed?

Multiple myeloma (MM) is a cancer that forms in plasma cells – a type of white blood cells, that gather in the bone marrow. Although there are many treatment options for people diagnosed with multiple myeloma, cancer often returns after their first treatment (relapsed MM), or cancer does not respond to treatment (refractory MM). Additional treatment options are needed.

Forimtamig is a type of drug called a T-cell bispecific antibody. It works by attaching to certain proteins on myeloma cells as well as T cells in the immune system which brings them closer together to help the immune system destroy the myeloma cells. Researchers hope that forimtamig will improve health outcomes for people with relapsed or refractory MM (RRMM).

This clinical trial aims to test the safety of forimtamig and how well it works at different doses, and to understand how the body processes forimtamig.

2. How does the BP42233 clinical trial work?

This clinical trial is recruiting people with RRMM. People can take part if there are no standard treatments available to them (including if standard treatment causes unacceptable side effects).

People who take part in this clinical trial (participants) will be given the clinical trial treatment forimtamig for up to 1 year (or up to 2 years if treatment is benefiting them), unless their MM worsens, or they have unacceptable side effects. Participants will be required to stay overnight in the hospital the first few times they are given forimtamig for safety monitoring. The clinical trial doctor will see them regularly, including several visits per week for the first month of the trial. After the last dose of treatment, participants will attend a follow-up visit 1 month later, then every 3 months for as long as they agree to it, or until their MM progresses or they start a different MM treatment. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time of participation in the clinical trial will be about 2 years plus follow-up visits. Participants who benefit from 1 year of forimtamig treatment but have cancer that progresses after the last dose may be able to restart forimtamig treatment for up to 1 more year. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BP42233 clinical trial?

The main clinical trial endpoints (the main results measured in the trial) are the number and seriousness of side effects and the maximum dose that can be given before unacceptable side effects occur.

The other clinical trial endpoints include:

- How the body processes forimtamig
- The number of participants whose cancer improves (objective response rate)
- If participants' cancer worsens, the amount of time between participants' cancer getting better from treatment and then getting worse (duration of response)
- How long participants live without their cancer worsening (progression-free survival)
- How long participants live (overall survival)

- How forimtamig affects the immune system
- How well participants tolerate forimtamig side effects and their impact on daily activities and quality of life

4. Who can take part in this clinical trial?

People with RRMM that have no standard treatment available to them can take part in this trial if they agree to provide samples of their tumour.

People may not be able to take part in this trial if they have uncontrolled cancer pain, have been given certain treatments including stem cell transplant shortly before starting the trial or organ transplant, or if they have certain other medical conditions including auto-immune disorders, any recent or ongoing infections, a history of other cancers, heart or lung disease, a history of or current diseases of the brain or spinal cord such as stroke, epilepsy, or MM that has spread to the brain or spinal cord, or are pregnant or breastfeeding.

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

The trial is in two parts – Part 1 will explore how often to give forimtamig and the safest dose to use when given as an infusion into a vein or as an injection under the skin. The results of Part 1 will be used in Part 2 to look at the safest and most effective way to give forimtamig in a larger number of participants.

Everyone who joins this clinical trial will be given forimtamig as an infusion (into the vein) or as an injection (under the skin) every 2, 3 or 4 weeks for up to 2 years unless their MM worsens, or they have unacceptable side effects. For safety reasons, the first few doses of forimtamig will be smaller than the intended target dose (called ‘step-up dosing’).

If a participant experiences a potential side effect called ‘cytokine release syndrome’ (when the immune system releases large amounts of inflammatory substances throughout the body), they may have to stay in the hospital for a longer period to be monitored and may be given a drug called tocilizumab as an infusion (into the vein) to treat the symptoms.

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 forimtamig and tocilizumab and possible side effects based on laboratory studies, knowledge of similar drugs and the experience from participants treated so far. Participants will be told about any known side effects of intravenous infusions and 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.