ForPatients
by Roche

Solid Tumors

A clinical trial to look at how safe RO7284755 is at different doses and how well it works alone or together with atezolizumab to reduce solid tumours

An open label, multicenter, randomized dose escalation and extension, phase Ia/Ib study to evaluate safety and anti-tumor activity of RO7284755, a PD-1 targeted IL-2 variant (IL-2v) immunocytokine, alone or in combination with atezolizumab in participants with advanced and/or metastatic solid tumors

Trial Status	Trial Runs In	Trial Identifier
Recruiting	6 Countries	NCT04303858 2023-503749-76-00 BP41628

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 an entry-into-human study and will assess the effects of eciskafusp alfa (RO7284755) as a single agent and in combination with atezolizumab in adult participants with solid tumors considered responsive to checkpoint inhibition blockade. The maximum duration in the study for each participant will be up to 28 months.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT04303858 2023-503749-76-00 BP41628
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the BP41628 clinical trial needed?

Solid tumours are cancer cells that grow in organ systems throughout the body. The BP41628 clinical trial is looking at a new treatment for advanced solid tumours. Advanced cancer is often a large tumour. It may have started spreading in the body. It usually affects

surrounding tissues or lymph nodes first. It can also be a tumour that has come back after being treated.

This trial is looking at 2 drugs - RO7284755 and atezolizumab. These are known as ‘immunotherapy’. Immunotherapy is a type of medicine that helps a person’s immune system attack cancer cells. RO7284755 contains a modified version of a protein the body naturally makes called ‘interluekin-2’ (IL-2). IL-2 activates the immune system. RO7284755 also blocks a protein called ‘PD-1’. Atezolizumab blocks a protein called ‘PD-L1’. PD-1 and PD-L1 protect the body’s healthy cells from attack by the immune system. But cancer cells that have PD-L1 can also be protected. By blocking PD-1 and PD-L1, and by activating the immune system with IL-2, RO7284755 combined with atezolizumab may stop or reverse the growth of tumours.

RO7284755 is an experimental drug. This means health authorities have not approved RO7284755 on its own or combined with atezolizumab for treating people with advanced solid tumours. This clinical trial aims to compare the safety of RO7284755 at different doses. It will also assess how well it works on its own or combined with atezolizumab in people with advanced solid tumours. Additionally, the clinical trial will look at how the body processes the drugs.

2. How does the BP41628 clinical trial work?

This clinical trial is recruiting people with advanced solid tumours. People can take part if their cancer has spread or cannot be removed with surgery, AND if they have no other treatment options available for them or cannot be given standard treatments.

People who take part in this clinical trial (participants) will be given the clinical trial treatment RO7284755 on its own or combined with atezolizumab. Clinical trial treatment will be given for as long as it can help, until participants have intolerable unwanted effects or until the trial is stopped. The clinical trial doctor will see them regularly. These hospital visits will include checks to see how the participant responds to the treatment and any unwanted effects they may have. After the last dose of treatment, participants will have follow-up appointments 3 and 4 months later, then every 3 months for as long as they agree to it. Total time of participation in the clinical trial will be about 2 and a half years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BP41628 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see if the drugs have worked) are:

- The number and seriousness of unwanted effects of treatment
- How many participants have a specific level of reduction in the size of their tumour

The other clinical trial endpoints include:

- The number of people whose tumours do not grow or shrink after receiving treatment and the amount of time this lasts if the cancer then gets worse
- How long people live without their cancer getting worse
- How RO7284755 gets to different parts of the body
- How the body changes and gets rid of RO7284755
- The effects RO7284755 has on the immune system
- The change in the number of certain immune cells present in participants' blood during the trial
- The change in the number of PD-1 and PD-L1 proteins and abnormal genes during the trial

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged 18 years or older and meet the specific criteria for the part of the trial they join. People may not be able to take part in this trial if they have certain cancers such as untreated tumours in the brain or spinal cord. People also cannot take part if they had or have certain medical conditions. These include heart disease, liver disease, autoimmune disease, dementia or an active infection. People who have had certain treatments such as certain immunotherapies within the past month, cannot take part. People who are pregnant or breastfeeding or are planning to become pregnant up to 5 months after the last dose of treatment, also cannot take part.

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

Everyone in this clinical trial will join Part 1, Part 2 or Part 3. This will depend on when they join the trial. Participants will be given:

Part 1

- RO7284755 as a drip into the vein (infusion) OR a drip under the skin (subcutaneous injection)

Part 2

- RO7284755 as a drip into the vein (infusion)
- AND atezolizumab as a drip into the vein (infusion) every 3 weeks

Part 3

- RO7284755 OR RO7284755 and atezolizumab

Participants in Part 1 will be split into 2 groups randomly (like flipping a coin), with a 1 in 2 chance of being placed in either group. In Part 3, if more than 1 treatment group is available, participants will have an equal chance of being placed in any group.

Participants in Part 1 and 2 may be given RO7284755 once a week for 6 weeks, then every 2 or 3 weeks. OR every 3 weeks. OR, every 3 weeks participants may have a lower dose of RO7284755 on Day 1 and a higher target dose on Day 5 (called ‘step-up’ doses). In Part 3, the results of Parts 1 and 2 will decide how often treatment is given and whether a drip into a vein or under the skin is used.

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 unwanted effects from the drugs used in this clinical trial. Unwanted 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. RO7284755 has not yet been tested in humans. For this reason, this drug’s unwanted effects are not fully known now. Participants will be told about the possible unwanted effects based on laboratory studies or knowledge of similar drugs. Participants will also be told about the known unwanted effects of atezolizumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known unwanted effects of a drip into the vein and a drip under the skin.

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.

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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