ForPatients
by Roche

NeoplasmsMetastatic Solid TumorsAdvanced Solid Tumors

A study to see how safe is RO7567132 as single agent and in combination with atezolizumab, how the body gets rid of it and how effective it is in people with advanced and/or metastatic solid tumors

A Dose-escalation Study of RO7567132 as Single Agent and in Combination With Atezolizumab in Participants With Advanced Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Recruiting	7 Countries	NCT06537310 2024-512839-70-00 BP44956

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:

An Open-label, Multicenter, Dose-escalation, Randomized, Phase I Study to Evaluate Safety, Pharmacokinetics, Pharmacodynamics and Anti-Tumor Activity of RO7567132, as a Single Agent and in Combination With Atezolizumab in Participants With Advanced and/or Metastatic Solid Tumors

Trial Summary:

The purpose of this study is to evaluate the safety, pharmacokinetics (PK), pharmacodynamics (PD) and preliminary clinical activity of RO7567132 as single agent and in combination with atezolizumab. The study will enroll adult participants with selected locally advanced and/or metastatic solid tumors for whom standard therapy does not exist, or has proven to be ineffective or intolerable.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT06537310 2024-512839-70-00 BP44956
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. WHY IS THIS STUDY NEEDED?

Solid tumors are cancers that grow in organs anywhere in the body. Standard treatment includes surgery, chemotherapy, and medicines that help the body's natural defense (immune system) to fight cancer cells (known as "immunotherapy"). However, standard treatments do not work for everyone or stop working after a while. Therefore, new treatments are needed, especially for cancers that cannot be removed with surgery ("advanced cancer") or have spread to other parts of the body ("metastatic cancer").

This study is testing a medicine called RO7567132. It is an immunotherapy that is being developed for the possible treatment of cancer that has spread and has not responded to treatment.

This study aims to test how safe RO7567132 is at different doses, to understand what happens to RO7567132 once it is in the body, and to explore if it reduces the size of the tumors.

RO7567132 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and the European Medicines Agency) have not approved RO7567132 alone or in combination with atezolizumab for the treatment of cancer.

2. WHO CAN TAKE PART IN THE STUDY?

People aged 18 years and older with certain types of advanced cancer can take part in this study if their cancer did not respond or no longer responds to available standard treatments or if these treatments caused unmanageable side effects.

People may not be able to take part in this study if they have cancer that has spread to the brain or spinal cord, have certain ongoing medical conditions, or are pregnant or currently breastfeeding.

3. HOW DOES THIS STUDY WORK?

People will be evaluated by a study doctor to check if they are able to participate in the study. This assessment will be 2 to 4 weeks before the start of treatment.

The study has two parts. Everyone who joins the first part of the study will be randomly placed into one of two groups and given either RO7567132 alone or RO7567132 along with atezolizumab. All participants joining the second part of the study will be treated with RO7567132 along with atezolizumab.

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

During this study, the study doctor will see participants at least every week. The study doctor will see how well the treatment is working, if it is causing any unwanted side effects

and how extensive these side effects may be. Participants will have at least one follow-up visit 1 month after completing the study treatment during which the study doctor will check on the participant's wellbeing.

In addition, participants will receive a follow-up telephone call from the study doctor to check on their wellbeing every 3 months and up to a maximum of two years after starting treatment. The total time participants will spend in the study will be about 2 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 purpose of the study is to check if RO7567132 is safe. This is done by measuring the number and seriousness of any unwanted side effects that may occur after receiving the study treatment until up to 3 months after completing the treatment.

Other key results measured in the study include:

- The highest dose that can be given to participants before they experience any unacceptable, unwanted side effects.
- The dose that provides the most benefits, if any.
- What happens to RO7567132 at different doses in the body, starting with the first study treatment until completion of study treatment.

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 cancers in the future.

It may not be fully known at the time of the study, how safe and how well RO7567132 alone or together with atezolizumab 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 progression of their cancer. 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 also be described in an Informed Consent Form, which also includes information about possible side effects and other options of treatment.

Risks associated with the study drugs Participants may have unwanted side effects as a result of the medicines used in this study. These unwanted side effects can be mild to severe, even life-threatening, and will vary from person to person.

RO7567132 has not yet been tested in humans. Therefore, the unwanted side effects of this medicine are not known. Participants will be informed about the possible unwanted side effects seen in laboratory studies or based on knowledge of similar medicines.

RO7567132 and atezolizumab will be given either as an infusion (drip) into the vein or injection. RO7567132 and atezolizumab have never been tested together.

Some potential unwanted side effects of RO7567132 and known unwanted effects of atezolizumab include:

Reactions associated with infusion or injections such as fever, chills, itching, pain or swelling at the injection site.
Other possible unwanted side effects may include painful or swollen joints, breathing problems, inflammation of the intestines with possible pain and watery stool, blood clots stopping the flow of blood to the brain or heart, and slow or poor healing of wounds.
The study medicine(s) 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:

- Male or female participants aged #18 years
- Body weight > 40 kilograms (kg)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 and Life expectancy of at least 12 weeks
- Participants with advanced and/or metastatic solid tumors
- Availability and willingness to provide a mandatory archival tumor specimen or (if not available) a fresh baseline biopsy
- Negative serum pregnancy test
- Participants must have adequate cardiovascular, hematological, liver and renal function.

Exclusion Criteria:

- Known central nervous system (CNS) tumors or metastases and leptomeningeal metastases
- Active second malignancy within 2 years prior to screening
- History or current clinically significant cardiovascular/cerebrovascular disease
- Active or history of autoimmune disease
- Serious, uncontrolled infection
- Known clinically significant liver disease
- Unresolved acute toxicity > grade 1 from prior therapy