ForPatients
*by Roche*

Solid Tumors

# A study to evaluate safety, pharmacokinetics, and preliminary clinical activity of RO7276389 alone and in combination with cobimetinib in participants with BRAF-V600 mutation-positive advanced solid tumor or BRAF-V600 mutation-positive melanoma with central nervous system metastases

A phase IA/B open-label study to evaluate safety, pharmacokinetics, and preliminary clinical activity of RO7276389 alone and in combination with cobimetinib in participants with Braf-V600 mutation-positive advanced solid tumor or Braf-V600 mutation-positive melanoma with central nervous system metastases

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Not Yet Recruiting | 1 Countries | 2023-506310-43-00 WP43295 |

*The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.*

## *Trial Summary:*

The aim of this open-label study is to evaluate the safety, tolerability, processing by the body and effectiveness against BRAF-mutated solid tumours or melanoma of RO7276389 by itself or in combination with cobimetinib

**F. Hoffmann-La Roche (USA)**
Sponsor

**2023-506310-43-00 WP43295**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| Both | >= 18 years | No |

### 1. Why is this study needed?

This study is testing a medicine called RO7276389. It is being developed to treat patients with metastatic or locally advanced solid tumors that contain an abnormal form of a protein called BRAF.

Metastatic cancer means that the cancer has spread from the place where it started to another part of the body. Locally advanced cancer means that the cancer has spread to nearby tissues but has not yet spread to other parts of the body.

Specifically, patients with melanoma with an abnormal form of the BRAF protein are included in this study. Melanoma is a type of skin cancer that occurs when the cells responsible for giving colour to the skin start to grow in a harmful and uncontrollable way.

RO7276389 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7276389 (alone or in combination with cobimetinib) for the treatment of melanoma or any other type of tumor.

This study aims to test how safe RO7276389 (at different doses) is and to understand what happens to RO7276389 once it is in the body. In addition, RO7276389 is tested together with a molecule called cobimetinib. The reason for testing this combination is as follows: Other studies have shown that adding cobimetinib to medicines similar to RO7276389 may improve how well the drug works.

**2. Who can take part in the study?**

People aged 18 years or older with solid tumors can take part in the study if their tumor contains an abnormal form of a protein called BRAF. This protein is normally found in all cells of the body, but an abnormal form is only found in tumors.

People may not be able to take part in this study if the tumor has not spread or is not locally advanced.

People who are 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 to 1 day before the start of treatment.

Everyone who joins this study will be given RO7276389 as tablets to swallow once, twice, or three times a day. Participants who also need to take cobimetinib will take additional tablets once a day three weeks in a row. This will be followed by one week during which no cobimetinib tablets need to be taken. This 3 weeks with cobimetinib/1 week without cobimetinib scheme will continue during the entire study.

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.

At the beginning of the study, the study doctor will see participants every few days and then once a month later on in the study. The study doctor will see how well the treatment is working and any unwanted effects participants may have. Participants will have at least two follow-up visits after study treatment has finished, one after 28 days and then every 3 months, during which the study doctor will check on the participant's wellbeing. The total time of study treatment will be up to 2 years. This time may be longer if the study doctor and Roche believe it may be beneficial for the participant. 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 this study are to find out whether a safe and effective dose of RO7276389, alone or in combination with cobimetinib, can be found that could be used in future studies. Other key results measured in the study are to see how RO7276389 alone, or in combination with cobimetinib, gets to different parts of the body, and how the body gets rid of it.

**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 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 drugs**

Participants may have unwanted effects of the drugs 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.

**RO7276389 and Cobimetinib**

Participants will be told about the known unwanted effects of RO7276389 and cobimetinib and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. The most commonly known unwanted effects of drugs that are similar to RO7276389 include rash, itching, and dry skin, frequent watery stools, nausea, vomiting, joint pain, fever, fatigue, and changes in vision.

Additional risks associated with cobimetinib include bleeding episodes, heart problems, breakdown of muscle tissue with possible kidney problems, buildup of fluid under the retina in the eye, blurred vision, watery stools, nausea, vomiting, rash, high blood pressure, and fever.

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.