ForPatients
by Roche

Squamous Cell Carcinoma

A study to look at how safe inavolisib is with or without atezolizumab, and how well these study medicines work against cancer that has changes in the PIK3CA gene

A Phase I/Ib study evaluating single-agent inavolisib and inavolisib plus atezolizumab in PIK3CA-mutated cancers

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	3 Countries	CO43909

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

Trial Summary:

A study to evaluate single-agent inavolisib and inavolisib plus atezolizumab in PIK3CA-mutated cancers

F. Hoffmann-La Roche Ltd (Switzerland), Genentech Inc (USA) Sponsor	**Phase 1** Phase

CO43909
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 years and Above	No

1. Why is this study needed?

Cancer is a health condition where the body's cells start growing and multiplying in an uncontrolled and abnormal way. These cells do not follow the usual pattern of cell division and growth. Instead, they form a lump or mass called a tumour. Head and neck squamous cell carcinoma (HNSCC) is a type of cancer that forms in the head or neck. For some people, the cancer spreads to other parts of the body (known as ‘metastatic’ cancer). Or the cancer returns after some time has passed when it could not be detected (known as ‘recurrent’ cancer).

Some cancers have a change in a gene called PIK3CA. A gene is a section of DNA that has instructions for making the body. Cells that have a changed PIK3CA gene are able to survive and grow out of control. They become cancers. Cancers with a change in PIK3CA are called ‘PIK3CA-positive’. Better treatments are needed for PIK3CA-positive cancers that are recurrent or have spread to other parts of the body.

This study is testing a medicine called inavolisib on its own and with another medicine called atezolizumab. They are being developed to treat PIK3CA-positive cancers. Health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have approved atezolizumab for treating certain cancers. Inavolisib and atezolizumab are experimental medicines in this study. This means health authorities have not approved them for the treatment of PIK3CA-positive cancers or HNSCC.

This study aims to test how safe inavolisib is with or without atezolizumab, and how well they work against PIK3CA-positive cancers. This study will also look at what happens to inavolisib once it is in the body.

2. Who can take part in the study?

People of 18 years of age or older can take part in the study if they have PIK3CA-positive HNSCC that has either spread to other parts of the body, is recurrent, or both. They must have also been treated for HNSCC after the cancer came back or spread.

People may not be able to take part in this study if:

- Their cancer can be treated with surgery and/or radiotherapy
- They have received certain treatments
- They have certain medical conditions, such as infections

People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 day to 1 month before the start of treatment.

Everyone who joins this study will be put into 1 of 2 groups. This will depend on when the participant joins the study and any other medical conditions they have. It will also depend on what treatments they have been given and if they can be given an intravenous or ‘IV’ infusion (drip into a vein given slowly).

Participants in Group A will be given:

- Inavolisib as a tablet to be swallowed once a day

Participants in Group B will be given:

- Inavolisib as a tablet to be swallowed once a day
- AND atezolizumab as an IV infusion every 3 weeks

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 regularly. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have up to 3 follow-up visits once a month after completing the study treatment, during which the study doctor will check on the participant's well-being. Then, follow-up visits will be every 2 to 3 months until a participant starts another treatment or their cancer gets worse. Total time of participation in the study could be more than 6 months. 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 result measured in the study to assess if the medicines have worked is the number and seriousness of unwanted effects.

Other key results measured in the study include:

- How many participants have a specific level of reduction in the size of their tumour that lasts for more than 1 month
- How many participants have a specific level of reduction in the size of their tumour
- How much time there is between the participant's cancer first responding to treatment and the cancer getting worse
- The number of participants whose tumours shrink or stay the same for at least 6 months with study treatment
- How long participants live without their cancer getting worse
- How inavolisib gets to different parts of the body, and how the body changes and 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.

Inavolisib and atezolizumab Participants will be told about the known unwanted effects of inavolisib and atezolizumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects of inavolisib include a high level of sugar in the blood, frequent watery stools, wanting to throw up, throwing up, rash, the inside linings of the body, like the mouth and nose, get irritated, and inflammation or ulcers of the lip or mouth. Known unwanted effects of atezolizumab include cough, pain or discomfort in the head, back, joints, muscles or bones, frequent watery stools, feeling less hungry than usual and feeling tired or weak. Known unwanted effects of IV infusions include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, reddening of the skin, pain or discomfort in the head, rapid heart rate, heart beat out of rhythm, frequent, watery stools, shortness of breath and cough.

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.