ForPatients
by Roche

Squamous Cell Carcinoma Squamous Cell Carcinoma of the Head and Neck (SCCHN)

A study of atezolizumab plus tiragolumab and atezolizumab plus placebo as first-line treatment in patients with recurrent/metastatic PD-L1 positive squamous cell carcinoma of the head and neck

A Study of Atezolizumab Plus Tiragolumab and Atezolizumab Plus Placebo as First-Line Treatment in Participants With Recurrent/Metastatic PD-L1 Positive Squamous Cell Carcinoma of the Head and Neck

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	13 Countries	NCT04665843 2023-509449-10-00 BO42533

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 primary objective of this study is to evaluate the efficacy of atezolizumab plus tiragolumab and atezolizumab plus placebo as first-line (1L) treatment in recurrent/ metastatic PD-L1-positive squamous cell carcinoma of the head and neck (SCCHN) on the basis of confirmed objective response rate. In addition, safety, pharmacokinetics, immunogenicity of atezolizumab and tiragolumab will be evaluated.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Squamous cell carcinoma of the head and neck (SCCHN) is a type of cancer that starts in the flat cells known as squamous cells. These cells are found in the moist layers of tissue (mucosal surfaces) that line the inside of certain parts of the body like the head and neck (inside the mouth, throat, voice box, etc). Despite advances in diagnosis and treatment of

early-stage SCCHN or SCCHN that has spread to nearby tissue (locally advanced) there is a high risk of cancer returning after treatment (recurrent) or spreading to other organs (metastasis). Hence, there is a constant need to find new treatments or combinations of treatments.

This study is testing the combination of medicines called atezolizumab and tiragolumab. It is being developed to treat SCCHN that has returned after treatment or has spread to other organs. Atezolizumab and the combination of atezolizumab plus tiragolumab are experimental treatments for SCCHN. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved atezolizumab or the combination for the treatment of SCCHN that has returned after treatment or has spread to other organs.

This study aims to compare the efficacy of atezolizumab plus tiragolumab and atezolizumab plus placebo each against a historical control arm in people with SCCHN. A historical control arm utilises data from participants who received the accepted standard treatment for SCCHN outside of the current study, allowing for a comparison with the treatment used in this study. Placebo is a medicine that contains no active ingredients but looks the same and is taken the same way as the study drug.

2. Who can take part in the study?

People who were at least 18 years old with SCCHN that has returned after treatment or has spread to other organs are taking part in the study. Only people who tested positive for a protein called programmed death ligand 1 (PDL-1) could participate in this study. PD-L1 is found on some cells, including cancer cells, which stops the body’s natural defence (immune system) from attacking them.

People could not take part in this study if they had any other significant health conditions or had a history of another type of cancer (other than SCCHN). People who received certain types of cancer therapies could not participate in this study. Women who were pregnant, or breastfeeding could not participate in the study.

3. How does this study work?

People were screened to check if they could participate in the study. The screening period took place for about 28 days before the start of treatment.

Everyone who joined this study was split into 2 groups (Groups A and B) randomly (like flipping a coin). Participants are receiving either atezolizumab plus tiragolumab (Group A), or atezolizumab plus placebo (Group B), as a drip into the vein (infusion), once every 3 weeks. Treatment will continue until participants are experiencing benefit from the treatment, their cancer worsens, or they experience any unacceptable unwanted effects. Participants had a 2:1 chance of being placed in any group.

This is a ‘placebo-controlled’ study. This means that participants are put in a group that is receiving medicine or a group that is receiving placebo. Comparing results from the two different groups helps researchers know if any observed changes result from the study medicine or occur by chance. This is a double-blinded study. This means that neither the participants in the study nor the team running it knows which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people expect from the received treatment. However, the study doctor can find out which group the participant is in, if the participant's safety is at risk.

During this study, the study doctor meets the participants every 3 weeks to see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit or will receive a telephone call every 3 months after completing the study treatment. These visits or telephone calls are for the study doctor to check on the participant’s well-being. The total time of participation in the study is expected to be around 43 months depending on how the cancer responds to treatment. 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 the study are the number of participants who are cancer-free or had at least a 30% reduction in their cancer. Other key results measured in the study include:

- Time between the person’s cancer first responding to treatment and the cancer getting worse
- Time between the start of treatment and signs that cancer is getting worse
- How long people live
- Number of participants with no signs of disease worsening after 6 months of treatment
- Number of participants alive after 6 and 12 months of treatment
- Time taken for a participant to have a significant worsening in physical and mental functioning assessed using a questionnaire from the start of the study until the completion of treatment
- Number of participants with unwanted effects
- How well the body processes tiragolumab and atezolizumab
- Number of participants whose bodies produce proteins that work against tiragolumab and atezolizumab

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 participants. 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 were informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study were described in an informed consent document. This includes information about possible effects and other options for 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 have regular check-ups to see if there are any unwanted effects.

Participants were told about the known unwanted effects of atezolizumab and tiragolumab and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Atezolizumab Known unwanted effects include back pain, feeling tired or weak (fatigue), joint pain (arthralgia), lack of energy (asthenia), decreased appetite, itching of the skin (pruritus), fever, rash, vomiting and muscle and bone pain (myalgia).

Tiragolumab Known unwanted effects include reaction to the infusion, inflammation of the liver (hepatitis), low levels of red blood cells (anemia), joint pain (arthralgia), decreased appetite, itching of the skin (pruritus), and rash.

Tiragolumab, atezolizumab, and placebo are given as a drip into the vein. Known unwanted effects include fever, chills, shortness of breath, rash, sensation of wanting to vomit (nausea), and changes in blood pressure.

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.

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04665843

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