ForPatients
by Roche

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

A clinical trial to evaluate atezolizumab plus tiragolumab and atezolizumab alone in people with 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	1 Countries	NCT04665843 2020-002852-19 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

NCT04665843 2020-002852-19 BO42533
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the BO42533 clinical trial work? This clinical trial is recruiting people who have a particular type of head and neck cancer called squamous cell carcinoma of the head and neck **(SCCHN)**. In order to take part, patients must have SCCHN that has come back after treatment from an earlier SCCHN diagnosis (recurrent) or SCCHN that has spread to other parts of the body (metastatic).

The purpose of this clinical trial is to study the effects, good or bad, of atezolizumab plus tiragolumab and atezolizumab alone in patients with SCCHN. In this clinical trial, you will get either atezolizumab plus tiragolumab or atezolizumab plus a placebo.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must be diagnosed with recurrent/metastatic SCCHN that has not been treated.

You must not have any other significant health conditions or have a history of another type of cancer (other than SCCHN) within the last 5 years. If you have previously received certain treatments within a particular amount of time before the study, you may not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into two groups:

- Group A will receive atezolizumab, given as an infusion into the vein every 3 weeks, and tiragolumab, also given as an infusion into the vein every 3 weeks
- Group B will receive atezolizumab, given as an infusion into the vein every 3 weeks, and a placebo, also given an infusion into the vein every 3 weeks

Twice as many people will be entered into Group A than Group B, meaning you will have a

2 in 3 chance of receiving atezolizumab plus tiragolumab and a 1 in 3 chance of receiving atezolizumab plus placebo

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a medicine with no active ingredients. A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment atezolizumab plus tiragolumab OR atezolizumab plus a placebo for as long as it can help you. You are free to stop this treatment at any time. You will be seen regularly by the clinical trial doctor every 3 weeks while you receive treatment. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

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

Trial-identifier: NCT04665843