ForPatients
by Roche

Esophageal Squamous Cell Carcinoma

A clinical trial to evaluate the safety and effectiveness of atezolizumab with or without tiragolumab versus placebo in people with squamous cell esophageal cancer that cannot be surgically removed and has not got worse after prior chemoradiotherapy (SKYSCRAPER-07)

A Study of Atezolizumab With or Without Tiragolumab in Participants With Unresectable Locally Advanced Esophageal Squamous Cell Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	28 Countries	NCT04543617 2020-001178-31 YO42137

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:

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab With or Without Tiragolumab (Anti-TIGIT Antibody) in Patients With Unresectable Esophageal Squamous Cell Carcinoma Whose Cancers Have Not Progressed Following Definitive Concurrent Chemoradiotherapy

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of tiragolumab plus atezolizumab compared with placebo in participants with unresectable esophageal squamous cell carcinoma (or those who are unable or unwilling to undergo surgery) and whose cancers have not progressed following definitive concurrent chemoradiotherapy (dCRT). Participants will be randomized in a 1:1:1 ratio to receive either tiragolumab plus atezolizumab (Arm A), tiragolumab matching placebo plus atezolizumab (Arm B), or double placebo (Arm C).

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Sponsor

Phase 3
Phase

NCT04543617 2020-001178-31 YO42137
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

How does the SKYSCRAPER-07 clinical trial work?

This clinical trial is recruiting people who have a type of cancer called squamous cell esophageal cancer. In order to take part, you must have been diagnosed with squamous cell esophageal cancer that cannot be surgically removed and has not got worse after prior chemoradiotherapy.

The purpose of this clinical trial is to evaluate the effects, good or bad, of tiragolumab plus atezolizumab or placebo plus atezolizumab versus placebo in people with squamous cell esophageal cancer that cannot be surgically removed and has not got worse after prior chemoradiotherapy.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with squamous cell esophageal cancer that cannot be surgically removed. You must have previously received chemotherapy treatment together with radiotherapy without any signs of your cancer getting worse.

You cannot join the trial if you are pregnant or breastfeeding. If you have certain other medical conditions or have previously received certain medications, you may not be able to take part. Vaccines for COVID-19 are permitted.

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, they 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 randomly into three equal groups:

- Tiragolumab plus atezolizumab, both given as infusions into your vein every three weeks
- OR atezolizumab plus placebo, both given as infusions into your vein every three weeks
- OR placebo plus placebo, both given as infusions in your vein every three weeks

You will have a 1 in 3 chance of being placed in any group.

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

This is a ‘double-blind’ clinical trial, which means neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor could find out which group you are in, if your safety is at risk

How often will I be seen for appointments and for how long?

You will be given the clinical trial treatment tiragolumab plus atezolizumab or placebo plus atezolizumab or placebo every three weeks for as long as it can help you, up to a total of 17 cycles. During these visits your clinical trial doctor will need to carry out scans and other medical assessments to see how your cancer is responding and any side effects that you may be having. You are free to stop this treatment at any time.

After you have finished treatment, your clinical trial doctor will contact you via telephone or through clinic visits approximately every three months or more frequently (as long as you agree to it). These follow-up appointments will check for any side effects from the clinical trial and see how your cancer is responding to any other treatments you may receive after the clinical trial.

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/NCT04543617

Trial-identifier: NCT04543617

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Histologically or cytologically confirmed diagnosis of squamous cell carcinoma of the esophagus
- Unresectable disease ineligible for curative surgery based on the documented opinion of the qualified medical, surgical or radiation oncologist prior to dCRT and is not expected to undergo tumor resection during the course of the study
- dCRT treatment according to regional oncology guidelines for esophageal cancer
- Representative archival formalin-fixed, paraffin-embedded (FFPE) tumor specimens collected prior to initiation of dCRT
- Adequate hematologic and end-organ function prior to randomization
- Women of childbearing potential must remain abstinent or use contraceptive methods with a failure rate of < 1% per year during the treatment period, for 5 months after the final dose of atezolizumab/placebo, and for 90 days after the final dose of tiragolumab/placebo, whichever is later
- Men must agree to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agree to refrain from donating sperm during the treatment period and for 90 days after the final dose of tiragolumab/placebo.

Exclusion Criteria:

- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, anti-PD-L1 and anti-TIGIT therapeutic antibodies
- Any unresolved toxicity of National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Grade # 2 from the prior chemoradiation therapy with the exception of irreversible and manageable hearing loss
- Prior allogeneic stem cell or solid organ transplantation
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis
- Malignancies other than esophageal cancer within 2 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Treatment with any other investigational agent, including epidermal growth factor receptor (EGFR) inhibitors, with therapeutic intent for esophageal cancer prior to randomization.