ForPatients
by Roche

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

A clinical trial to compare atezolizumab with a placebo in people with head and neck cancer who are at a high risk of their cancer returning or getting worse after completion of standard initial therapy.

A Study of Atezolizumab (Anti#Pd-L1 Antibody) as Adjuvant Therapy After Definitive Local Therapy in Patients With High-Risk Locally Advanced Squamous Cell Carcinoma of the Head and Neck

Trial Status	Trial Runs In	Trial Identifier
Terminated	23 Countries	NCT03452137 2017-003302-40 WO40242

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, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) as Adjuvant Therapy After Definitive Local Therapy in Patients With High-Risk Locally Advanced Squamous Cell Carcinoma of the Head and Neck

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab compared with placebo as adjuvant therapy after definitive local therapy in patients with high-risk locally advanced squamous cell carcinoma of the head and neck (SCCHN)

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03452137 2017-003302-40 WO40242
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the IMvoke010 clinical trial work?

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This clinical trial is recruiting people who have a particular type of head and neck cancer. In order to take part, patients must have advanced cancer of the head and neck that has not yet spread to distant parts of the body.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab against placebo in patients with head and neck cancer who have completed standard initial therapy and are at high risk of their cancer coming back or getting worse. If you take part in this clinical trial, you will receive either atezolizumab or a placebo.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with advanced head and neck cancer that has not yet spread to distant parts of the body. You must have already had initial treatment for your cancer (such as surgery, chemotherapy, radiotherapy or a mixture of these).

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, women who 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 2 groups randomly (like flipping a coin) and given either:

- Atezolizumab as an infusion into your vein every 3 weeks
- OR a placebo as an infusion into your vein every 3 weeks

You will have an equal chance of being placed in either group.

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This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given an infusion 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.

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 OR placebo for as long as you are tolerating the treatment and your cancer has not come back or gotten worse, up to a maximum of 1 year. You are free to stop this treatment at any time. During and after clinical trial treatment, you will receive scans regularly to assess how your cancer is responding to the treatment. These scans will continue until your cancer comes back or worsens or until you decide to leave the trial. After your treatment and scans have ended, you will still be seen regularly by the clinical trial doctor, or contacted by phone, every 3 months until the end of 5 years to help doctors understand any long-term impacts of the study on your health.

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/NCT03452137

Trial-identifier: NCT03452137

Inclusion Criteria:

- Histologically or cytologically confirmed Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- Human Papilloma Virus (HPV) status
- Completed definitive local therapy
- Absence of metastatic disease as documented by radiographic scans
- Adequate hematologic and end-organ function
- For patients receiving therapeutic anticoagulation: stable anticoagulant regimen
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for 5 months after the last dose of study treatment. Women must refrain from donating eggs during this same period.

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- Confirmed response of Complete Response (CR), Partial Response (PR), or Stable Disease (SD) to definitive local therapy documented by CT with contrast or MRI with contract to head and neck region done >= 8 weeks after completion of definitive local therapy and within 28 days prior to initiation of study drug.

Exclusion Criteria:

- Patients who have received surgery alone or radiotherapy alone as definitive local therapy
- Squamous cell carcinoma of the nasopharynx or paranasal sinuses or non-squamous histology
- Evidence of disease progression or metastatic disease during or following definitive local therapy documented in post-definitive local therapy screening scans
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency
- Active tuberculosis
- Significant cardiovascular disease
- History of malignancy, including prior SCCHN primary tumors within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Prior allogeneic stem cell or solid organ transplantation
- Current treatment with anti-viral therapy for Hepatitis B Virus (HBV)
- Treatment with systemic immunostimulatory agents
- Treatment with systemic immunosuppressive medication
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the last dose of study treatment
- Patients who have received a non-FDA or non-EMA approved anti-EGFR agent or any other non-FDA or non-EMA, approved agent as part of definitive local therapy, unless the unapproved agent was given in addition to an approved agent
- Any systemic therapies after permitted definitive local therapies

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