ForPatients
by Roche

Cervical Cancer

A clinical trial to evaluate tiragolumab plus atezolizumab and atezolizumab on its own in people with cervical cancer (SKYSCRAPER-04)

A Study of Tiragolumab Plus Atezolizumab and Atezolizumab Monotherapy in Participants With Metastatic and/or Recurrent PD-L1#Positive Cervical Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	17 Countries	NCT04300647 2019-004895-21 WO42017

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase II, Safety, and Efficacy Study of Tiragolumab Plus Atezolizumab and Atezolizumab Monotherapy in Patients With Metastatic and/or Recurrent PD-L1-Positive Cervical Cancer

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of tiragolumab in combination with atezolizumab and atezolizumab monotherapy in patients with programmed death-ligand 1 (PD-L1)-positive cervical cancer (metastatic and/or recurrent).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04300647 2019-004895-21 WO42017
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years	No

How does the WO42017 clinical trial work? This clinical trial is recruiting people who have a type of disease called cervical cancer. In order to take part, patients must have metastatic (spread to other parts of the body) and/or recurrent (returned after previous treatment) cervical cancer.

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

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must have been diagnosed metastatic and/or recurrent cervical cancer. You cannot join the trial if you are pregnant or breastfeeding.

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, if you are not currently pregnant but can become pregnant, you 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 and given either:

- Group A - tiragolumab plus atezolizumab, given as infusions into the vein every 3 weeks
- OR Group B - atezolizumab on its own given as an infusion into the vein every 3 weeks

More people will be assigned to Group A than Group B. Everyone who joins this clinical trial will have a 3 in 4 (75%) chance of being placed in Group A and a 1 in 4 chance (25%) of being placed in Group B. This study is ‘open label’, which means that everyone involved will know what group they are in and what treatment they are receiving.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment tiragolumab plus atezolizumab OR atezolizumab on its own for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor every 3

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months. 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

Trial-identifier: NCT04300647

Inclusion Criteria:

- Histologically confirmed recurrent or persistent squamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix after progression on or after 1-2 lines of prior systemic chemotherapy in the metastatic/recurrent setting that is not amenable to curative treatment with systemic chemotherapy, surgery, and/or radiotherapy
- Radiologically-measurable disease
- Eastern Cooperative Oncology Group (ECOG) performance Status of 0 or 1
- Cervical cancer tissue for study analysis (archival or fresh biopsy specimen)
- Life expectancy of at least 12 weeks
- Adequate hematologic and organ function
- Female of childbearing potential must be willing to comply with adequate contraception

Exclusion Criteria:

- Treatment with investigational therapy with therapeutic intent within 28 days prior to randomization
- Active or untreated central nervous system (CNS) or brain metastases
- Active or history of autoimmune disease or immune deficiency
- Active tuberculosis
- Known, clinically significant liver disease
- Severe infection per investigator judgement at the time of randomization or any active infection that, in the opinion of the investigator, could impact patient safety
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-CTLA-4, anti-TIGIT, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 drug-elimination half-lives (whichever is longer) prior to randomization
- Treatment with systemic immunosuppressive medications within 1 week prior to randomization or anticipation of need for systemic immunosuppressive medication during study
- Pregnant or breastfeeding woman
- Known hypersensitivity to any component of the tiragolumab or atezolizumab formulations

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