ForPatients
by Roche

Cáncer Cervicouterino

WO42017 Estudio de tiragolumab más atezolizumab y atezolizumab en monoterapia en participantes con cáncer cervical metastásico y/o recurrente positivo para PD-L1 (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
Finalizado	17 Countries	NCT04300647 2019-004895-21 WO42017

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

Estudio fase II para evaluar eficacia y seguridad de tiragolumab en combinación con atezolizumab y monoterapia con atezolizumab en pacientes con cáncer cervical metastásico y/o recurrente positivo para PD-L-1

Trial Summary:

El objetivo de este estudio es evaluar la seguridad y eficacia de tiragolumab en combinación con atezolizumab y la monoterapia con atezolizumab en pacientes con cáncer cervicouterino (metastásico y/o recurrente) positivo para ligando de la muerte programada 1 (PD-L1, por sus siglas en inglés).

Hoffmann-La Roche Sponsor	**Fase 1, Fase 2** 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.

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 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 https://clinicaltrials.gov/ct2/show/NCT04300647

Trial-identifier: NCT04300647

Inclusion Criteria:

- Carcinoma de células escamosas, carcinoma adenoescamoso o adenocarcinoma de cuello uterino persistente o recurrente confirmado histológicamente, después de al menos 1 línea de terapia previa, que no es susceptible al tratamiento curativo con quimioterapia sistémica, cirugía y/o radioterapia
- Enfermedad cuantificable mediante radiología
- Estado funcional del Grupo oncológico cooperativo del este (ECOG) de 0 o 1
- Tejido del cáncer cervicouterino para el análisis del estudio (muestra preservada o de biopsia reciente)
- Esperanza de vida de al menos 12 semanas
- Función hematológica y orgánica adecuada
- Las mujeres con capacidad de concebir deben estar dispuestas a cumplir con un método anticonceptivo adecuado

Exclusion Criteria:

- Tratamiento con una terapia en investigación con intención terapéutica en los 28 días previos a la aleatorización.
- Cualquier metástasis cerebral o en el sistema nervioso central (SNC)
- Antecedentes o enfermedad autoinmunitaria o inmunodeficiencia activa
- Tuberculosis activa
- Hepatopatía conocida clínicamente significativa
- Infección severa en el momento de la aleatorización
- Infección conocida por el virus de inmunodeficiencia humana (VIH)
- Tratamiento previo con agonistas de CD137 o terapias de bloqueo de puntos de control inmunitario y anticuerpos terapéuticos antiCTLA-4, anti-TIGIT y anti-PD-L1.
- Tratamiento con agentes inmunoestimulantes sistémicos dentro de las 4 semanas o 5 vidas medias de eliminación del medicamento (lo que sea más extenso) antes de la aleatorización
- Tratamiento con medicamentos inmunosupresores sistémicos dentro de la semana previa a la aleatorización o anticipación de la necesidad de cualquier medicamento inmunosupresor sistémico durante estudio
- Mujer en embarazo o en lactancia.

- Hipersensibilidad conocida a cualquier componente de las formulaciones de tiragolumab o atezolizumab