ForPatients
by Roche

Renal Cell Cancer (RCC)Renal Cell Carcinoma

A Clinical Trial of Atezolizumab in Patients with Renal Cell Carcinoma that is at High Risk of Coming Back After Surgery (IMmotion010)

A Study of Atezolizumab as Adjuvant Therapy in Participants With Renal Cell Carcinoma (RCC) at High Risk of Developing Metastasis Following Nephrectomy (IMmotion010)

Trial Status	Trial Runs In	Trial Identifier
Terminated	28 Countries	NCT03024996 2016-001881-27 WO39210

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, Placebo-Controlled, Double-Blind Study of Atezolizumab (Anti-PD-L1 Antibody) as Adjuvant Therapy in Patients With Renal Cell Carcinoma at High Risk of Developing Metastasis Following Nephrectomy

Trial Summary:

This is a Phase III, multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of atezolizumab versus placebo in participants with RCC who are at high risk of disease recurrence following nephrectomy.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03024996 2016-001881-27 WO39210
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the IMmotion010 clinical trial work?

This clinical trial is recruiting people who have had a type of kidney cancer called ‘renal cell carcinoma’ or RCC, which has been removed with surgery. The aim of the clinical trial is to stop or delay your RCC from coming back.

This clinical trial is for people who have not been given any treatment known as ‘immunotherapy’ (treatment that helps your own immune system to kill cancer) for their cancer and have had surgery to remove some or all of the kidney (known as a partial or full ‘nephrectomy’).

How do I take part in this clinical trial? 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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of 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 and procedures may be part of your regular medical care and 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 and what other treatments are available so that you may decide if you still want to take part.

What treatment will I be given if I join this clinical trial? If you agree to take part in this clinical trial, and your doctor confirms that you are at high risk of your cancer coming back around your kidney or other parts of your body, then you may be able to be given treatment for your specific type of cancer.

Everyone who joins the clinical trial will be split into two groups randomly (like flipping a coin) and given one of two different treatments. You will either be given the new medicine atezolizumab or you will be given an alternative with no active drug (called a ‘placebo’). Some people will be given a placebo to help the doctors see whether any effects seen with the test medicine, atezolizumab, are real or not. You will be given the treatment into your vein (this is called an ‘intravenous infusion’) once every 3 weeks for a maximum of 16 cycles (each cycle is 21 days) or 1 year (whichever occurs first).

How often will I be seen in follow-up appointments, and for how long? Before you are given each treatment, at the beginning of each treatment cycle, you will need to have blood tests. You will also meet your doctor several times a year until the end of the clinical trial to talk about how you are responding to the treatment (if your cancer has not come back) and any side effects that you may be having.

What happens if I'm unable to take part in this clinical trial?

If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03024996

Inclusion Criteria:

- ECOG performance status of less than or equal to (</=) 1
- Pathologically confirmed RCC with a component of either clear cell histology or sarcomatoid histology that has not been previously treated in the adjuvant or neoadjuvant setting and classified as being at high risk of RCC recurrence
- Radical or partial nephrectomy with lymphadenectomy in select participants
- Absence of residual disease and absence of metastasis, as confirmed by a negative baseline computed tomography (CT) of the pelvis, abdomen, and chest no more than 4 weeks prior to randomization. Confirmation of disease-free status will be assessed by an independent central radiologic review of imaging data.
- Absence of brain metastasis, as confirmed by a negative CT with contrast or magnetic resonance imaging (MRI) scan of the brain, no more than 4 weeks prior to randomization. Applicable only to metastasectomy participants
- Full recovery from nephrectomy or metastasectomy within 12 weeks from randomization following surgery

Exclusion Criteria:

- Bilateral synchronous tumors with inheritable forms of RCC including von Hippel-Lindau
- Any approved anti-cancer therapy, including chemotherapy or hormonal therapy, within 3 weeks prior to initiation of study treatment
- Treatment with any other investigational agent or participation in another clinical study with therapeutic intent within 28 days or five half-lives of the investigational agent, whichever is longer, prior to enrollment
- Malignancies other than RCC within 5 years prior to Cycle 1, Day 1
- History of autoimmune disease
- Participants with prior allogeneic stem cell or solid organ transplantation
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest CT scan
- Positive test for HIV
- Participants with active hepatitis B or hepatitis C
- Active tuberculosis
- Severe infections within 4 weeks prior to randomization including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia

- Major surgical procedure within 4 weeks prior to randomization or anticipation of need for a major surgical procedure during the course of the study other than for diagnosis
- Administration of a live, attenuated vaccine within 4 weeks before Cycle 1, Day 1
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the participant at high risk from treatment complications
- Prior treatment with cluster of differentiation (CD)137 agonists, anti-cytotoxic T-lymphocyte-associated protein-4 (anti-CTLA-4), anti-programmed death-1 (anti-PD-1), or anti-programmed death-ligand 1 (anti-PD-L1) therapeutic antibody or pathway-targeting agents
- Treatment with systemic immunostimulatory agents (including but not limited to interferons or interleukin-2) within 6 weeks or five half-lives of the drug, whichever is shorter, prior to randomization
- Treatment with systemic immunosuppressive medications (including but not limited to corticosteroids, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents) within 2 weeks prior to randomization or anticipated need for systemic immunosuppressive medications during the study