ForPatients
by Roche

Urothelial Cancer

A clinical trial to compare the effects of RO7247669 (also called 'PD1-LAG3') alone or in combination with tiragolumab versus atezolizumab in people with previously untreated urothelial cancer

A Study Evaluating Different Immunotherapies (LAG-3 and PD-1 With or Without TIGIT, Compared to PD-L1 Alone) in Participants With Untreated Locally Advanced Metastatic Urothelial Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	15 Countries	NCT05645692 BO44157

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of tobemstomig alone or in combination with tiragolumab compared with atezolizumab in participants with previously untreated, locally advanced or metastatic urothelial cancer (mUC) who are ineligible to receive a platinum containing chemotherapy.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT05645692 BO44157
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the BO44157 clinical trial needed?

Urothelial cancer (which is often called 'bladder cancer') is a disease in which abnormal cells in the bladder or urinary tract divide and grow to form a tumour. Urothelial cancer can be described as 'locally advanced' (if the cancer has grown outside of its original area but has not yet spread to other parts of the body), or 'metastatic' (if the cancer has spread to other parts of the body).

The current standard-of-care for people with locally advanced or metastatic urothelial cancer is chemotherapy. People who cannot be given chemotherapy can be treated with a type of drug that stimulates the body's immune system to attack tumours (known as immunotherapy), such as atezolizumab. Atezolizumab can be a very effective drug and is approved for the treatment of different types of cancers in several countries. However, atezolizumab treatment can eventually stop working because the cancer becomes 'resistant' to the drug, and some people have cancers that do not respond at all to atezolizumab treatment.

New immunotherapy treatments for advanced and metastatic urothelial cancer are needed. In this trial, researchers are assessing the immunotherapy drugs RO7247669 (which is also called 'PD1-LAG3') and tiragolumab, which may help the immune system stop or reverse the growth of tumours.

Researchers hope that new immunotherapy drugs will provide better health outcomes for people with urothelial cancer.

2. How does the BO44157 clinical trial work?

This clinical trial is recruiting people who have locally advanced or metastatic urothelial cancer and who cannot receive treatment with chemotherapy.

The purpose of this clinical trial is to compare the effects, good or bad, of RO7247669 (PD1-LAG3) alone or in combination with tiragolumab versus atezolizumab in people with locally advanced or metastatic urothelial cancer. Participants who take part in this clinical trial will receive either RO7247669 (PD1-LAG3) alone, RO7247669 (PD1-LAG3) in combination with tiragolumab or atezolizumab alone.

Participants will be given the clinical trial treatment for as long as it helps, or until they leave the trial for any reason (for example, if their cancer worsens or they have unacceptable side effects). Participants will be seen by the clinical trial doctor every 3 weeks. Visits may last 1#8 hours. These hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants' total time in the clinical trial will depend on how they tolerate the treatment and how their cancer responds to treatment. This could range from 1 day to more than 30 months. Participants are free to stop trial treatment and leave the clinical trial at any time. After participants stop treatment, they will still have follow-up appointments with the clinical trial doctor every 3 months for as long as they agree to this.

3. What are the main endpoints of the BO44157 clinical trial?

The main clinical trial endpoint (the main result that is measured in the trial to see if the medicine has worked) is to assess how many participants have a change in tumour size or how much the disease had progressed (known as the ‘objective response rate’).

The other clinical trial endpoints include:

To assess how much time there is between the start of the trial and the participant’s cancer getting worse (known as ‘progression-free survival’)

To assess how long participants live (known as ‘overall survival’)

To assess how much time there is between the participant’s cancer first responding to treatment and the cancer getting worse (known as ‘duration of response’)

To assess how many participants have a change in tumour size or how much the disease has progressed up to 12 weeks (known as ‘disease control rate’)

The number and seriousness of any side effects

To assess the quality of life of participants, and

How the body processes and responds to RO7247669 (PD1-LAG3) alone or in combination with tiragolumab

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and have been diagnosed with urothelial cancer that is either locally advanced or metastatic and cannot receive a certain type of chemotherapy, known as platinum-based chemotherapy.

People may not be able to take part in this trial if they have metastatic brain cancer (unless it is in a specific location and has been treated with radiotherapy) or spinal cord cancer, previously received certain treatments, are pregnant or breastfeeding or are planning to become pregnant.

5. What treatment will participants be given in this clinical trial?

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which medicine is being used. Neither the participant nor the clinical trial

doctor can choose the group the participant is in. Everyone who joins this clinical trial will be split into one of three groups randomly (like flipping a coin):

Group 1: Atezolizumab, given as an intravenous injection (into a vein) once every 21 days

Group 2: RO7247669 (PD1-LAG3), given as an intravenous injection (into a vein) once every 21 days

Group 3: RO7247669 (PD1-LAG3) plus tiragolumab, given as an intravenous injection (into a vein) once every 21 days.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Atezolizumab, RO7247669 (PD1-LAG-3), tiragolumab

Potential participants will be told about the known side effects of atezolizumab, RO7247669 (PD1-LAG3) and tiragolumab, and, where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Atezolizumab, RO7247669 (PD1-LAG3) and tiragolumab will be given an intravenous (into a vein) injection. Participants will be told about any known side effects of intravenous injections.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05645692