ForPatients
by Roche

PD-L1-selected Solid Tumors

A study to evaluate the safety and pharmacokinetics of the intravenous fixed-dose combination (IV FDC) of tiragolumab and atezolizumab in participants with locally advanced, recurrent or metastatic solid tumors

A Study to Evaluate the Safety and Pharmacokinetics of the Intravenous Fixed-Dose Combination (IV FDC) of Tiragolumab and Atezolizumab in Participants With Locally Advanced, Recurrent or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	9 Countries	NCT05661578 2022-001157-23 2023-508489-14-00 GO44096

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 II, single-arm, open-label study evaluating the safety and pharmacokinetics of the intravenous fixed-dose combination (IV FDC) of tiragolumab and atezolizumab in participants with locally advanced, recurrent, or metastatic solid tumors

Trial Summary:

The purpose of this study is to assess the safety, pharmacokinetics, and immunogenicity of tiragolumab and atezolizumab intravenous fixed-dose combination (IV FDC) in participants with histologically confirmed PD-L1-selected solid tumors whose disease is locally advanced, recurrent, or metastatic and for whom an investigational agent in combination with an anti-PD-L1 antibody is considered an acceptable treatment option.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT05661578 2022-001157-23 2023-508489-14-00 GO44096
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is this study needed?

Cancer is a health condition where the body's cells start growing and multiplying in an uncontrolled and abnormal way. Cancer can be difficult to treat if it spreads to other organs in the body. However, new type of medicines that helps the body's natural defence mechanism (immune system) to attack the cancerous cells (immunotherapies), have shown encouraging results for the treatment of cancer.

This study is testing a combination of drugs called tiragolumab and atezolizumab, which is being developed to treat cancer that has spread in nearby cells, has come back, or that has spread to other parts of the body. This is the first time that the combination of tiragolumab and atezolizumab in one bottle will be administered to patients. This combination is being explored to try and simplify the administration of the two drugs and reduce the time that patients spend in the clinic.

Tiragolumab is an experimental medicine which means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved tiragolumab (alone or in combination with atezolizumab) for the treatment of cancer.

This study aims to look at the safety and effects (good or bad) of tiragolumab in combination with atezolizumab, as well as understand the way the body processes these drugs in people with cancer that has spread in nearby cells, has come back, or that has spread to other parts of the body.

2. Who can take part in the study?

People can take part in this study if they are at least 18 years old. People diagnosed with specific types of cancer that has spread in nearby cells, has come back, or that has spread to other parts of the body and is positive for a protein known as PD-L1 can participate in this study. People who have run out of options for standard treatments can take part in this study. Participants should also be willing to allow a tumour sample to be taken to see if their tumour is positive for PD-L1.

People may not be able to take part in this study if they have certain other medical conditions such as heart and liver disease, have previously received certain treatments like checkpoint inhibitor therapies (for example, anti-PD-L1/PD-1). Checkpoint inhibitors are medicines that "release the breaks” on the immune system, allowing the immune system to recognize and attack cancer cells more effectively.

Participants who are pregnant, or currently breastfeeding cannot take part in this study.

3. How does this study work?

Participants may be a part of this study from 1 day to as long as the study doctor thinks that they are receiving benefit from the study treatment. Participants will be screened to check if they are eligible to participate in the study. The screening period will take place from Day 28 to Day 1 before the start of treatment.

Everyone who joins this study will be given tiragolumab and atezolizumab together from a single bottle an injection into the vein every 3 weeks. The treatment will be given until the participants' cancer gets worse, or they have unacceptable side effects (unwanted effects which may or may not be caused by study medicines).

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants every 3 weeks to see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit within 30 days after the final dose of the study treatment, during which the study doctor will check on the participant's wellbeing.
The study doctor will continue to check in with the participants on their wellbeing through telephone calls, clinic visits or medical records roughly every 3 months. Total time of participation in the study will depend on how the cancer responds to treatment. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main result measured in the study to assess if the medicine has worked is to assess the number and seriousness of any side effects of the study drugs. Other key results measured in the study are to understand the way the body processes tiragolumab and atezolizumab when given together from a single bottle, and how the body responds to these medicines.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant, but these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People who are interested in participating will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drugs

Participants may have unwanted effects of the drugs used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, regular check-ups will be done for participants to see if there are any unwanted effects.

Tiragolumab and atezolizumab

Tiragolumab and atezolizumab when given together from a single bottle have not yet been tested in humans. Therefore, the unwanted effects of these medicines together are not known now. Participants will be told about the possible unwanted effects based on laboratory studies or knowledge of similar medicines. Known unwanted effects of tiragolumab in combination with atezolizumab may include decreased level of red blood cells in the blood (anemia), joint pain (arthralgia), decreased appetite, itching of the skin (pruritus) and rash.

Tiragolumab and atezolizumab will be given by an injection into a vein (intravenous). Known unwanted effects include reactions associated with infusion which may include pain, bruising, or infection where the needle is inserted.

The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby or a breastfed baby to the study treatment.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy >=12 weeks
- Adequate hematologic and end organ function
- Recovery (i.e., improvement to Grade 1 or better) from all acute toxicities from previous therapy, excluding alopecia
- For female participants of childbearing potential, negative serum pregnancy test within 14 days prior to initiation of study treatment (Day 1 of Cycle 1)
- For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agree to refrain from donating eggs during the treatment period and for 5 months after the final dose of tiragolumab and atezolizumab IV FDC
- For male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agree to refrain from donating sperm during the treatment period and for 90 days after the final dose of tiragolumab and atezolizumab IV FDC to avoid exposing the embryo

Cancer-Specific Inclusion Criteria:

- Histologic documentation of locally advanced, recurrent, or metastatic malignancy, ineligible for definitive local therapy, for which a clinical trial of an investigational agent in combination with an anti-PD-L1 antibody is considered an acceptable treatment option. Participant must be informed of all standard of care options available for his/her cancer.
- No prior treatment with checkpoint inhibitor therapies (CPI-Naive)
- Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)

- Submittal of archival tumor and/or fresh tumor tissue to the central laboratory for programmed death-1 (PD-L1) evaluation prior to enrollment
- PD-L1 selected tumors, as determined by the investigational VENTANA PD-L1 (SP263) immunohistochemistry (IHC) assay

Exclusion Criteria:

- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 5 months after the final dose of tiragolumab and atezolizumab IV FDC
- Significant cardiovascular disease
- Known clinically significant liver disease
- Poorly controlled Type 2 diabetes mellitus
- Major surgical procedure within 28 days prior to Day 1 of Cycle 1 or anticipation of need for a major surgical procedure during the study
- Any other diseases, metabolic dysfunction, physical examination finding, and/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 may render the participant at high risk from treatment complications
- History of autoimmune disease
- Treatment with systemic immunosuppressive medications within 2 weeks prior to Day 1 of Cycle 1
- History of idiopathic pulmonary fibrosis, pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Severe infections within 4 weeks prior to Day 1 of Cycle 1 or recent infections/oral or IV antibiotics within 2 weeks prior to Day 1 of Cycle 1

Cancer-Specific Exclusion Criteria:

- Any anti-cancer therapy, whether investigational or approved within 3 weeks prior to initiation of study treatment
- Prior treatment with immune checkpoint inhibitors (CPIs)
- Less than 5 drug-elimination half-lives (~100 days for typical monoclonal antibody [Mab]) from the last dose of monoclonal antibodies (MAbs), and MAb-Derived Therapies (excluding CPIs) and the proposed Day 1 of Cycle 1
- Less than 6 weeks between the last dose of prior immunomodulators and the proposed Day 1 of Cycle 1
- Less than 6 weeks or 5-drug-elimination half-lives, whichever is shorter, of prior treatment with cancer vaccines and/or cytokines have elapsed between the last dose and the proposed Cycle 1, Day 1
- Any history of an immune-mediated Grade 4 adverse event attributed to prior cancer immunotherapy
- Any history of an immune-mediated Grade 3 adverse event attributed to prior cancer immunotherapy that resulted in permanent discontinuation of the prior immunotherapeutic agent and/or occurred </=6 months prior to Day 1 of Cycle 1
- Any immune-mediated adverse events related to prior cancer immunotherapy must have resolved completely to baseline
- Adverse events from prior anti-cancer therapy that have not resolved to Grade <=1 except for alopecia, vitiligo, or endocrinopathy managed with replacement therapy