

Câncer

Um ensaio clínico para continuar a fornecer tratamentos aos participantes que se beneficiaram em um ensaio com atezolizumabe patrocinado pela Genentech Inc. e/ou F. Hoffmann-La Roche Ltd

A Study in Patients Previously Enrolled in a Genentech and/or F. Hoffmann-La Roche Ltd Sponsored Atezolizumab Study

Trial Status
Ativo, sem recrutamento

Trial Runs In
25 Countries

Trial Identifier
NCT03768063 2023-506184-34-00
BO40729

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

An Open Label, Multicenter Extension Study in Patients Previously Enrolled in a Genentech and/or F. Hoffmann-La Roche Ltd Sponsored Atezolizumab Study (IMbrella B)

Trial Summary:

This is an open-label, multicenter, extension study. Patients who are receiving clinical benefit from atezolizumab monotherapy or atezolizumab in combination with other agent(s) or combination/comparator agent(s) during participation in a Genentech or Roche-sponsored study (the parent study), who are eligible to continue treatment and who do not have access to the study treatment locally, may continue to receive study treatment in this extension study following roll-over from the parent study.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

1. Why is the IMbrella B clinical trial needed?

This clinical trial aims to provide continued clinical trial treatments to people with cancer who take part in an atezolizumab-based trial that is sponsored by Genentech, Inc. and/or F. Hoffmann-La Roche Ltd (called parent trial) and who do not have access to the treatment locally.

People with cancer who benefit from treatment given in a clinical trial (meaning that their cancer shrinks or does not get worse) may continue to be given that treatment if there is no alternative treatment option and it is safe to do so, even if it is not approved by their health authority (such as the Food and Drug Administration (FDA), in the United States, or the European Medicines Agency (EMA)). They may also continue to receive the treatment after it is approved if their health insurance or other costs would prevent them from being able to have it.

2. How does the IMbrella B clinical trial work?

People can take part in this trial if they have cancer and were previously treated in an atezolizumab-based clinical trial sponsored by Genentech Inc. and/or F. Hoffmann-La Roche Ltd (called the 'parent trial'), and their cancer did not get worse when the parent trial closed.

People who take part in this clinical trial (participants) will be given the same clinical trial treatment as in the parent trial for as long as it can help them or until they have unacceptable side effects or the trial stops. This allows patients who benefit to continue taking a clinical trial treatment that is otherwise not available to them. The clinical trial doctor will see them regularly. These clinic visits will include checks to see how the participant responds to the treatment and any side effects they may have and will be the same as, or like, the checks that were done in the parent trial. The total time of participation in the clinical trial will depend on how the participant continues to respond to treatment, the local availability of the treatment and if the trial is stopped. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the IMbrella B clinical trial?

Since the purpose of this clinical trial is to provide continued clinical trial treatments – there is no main endpoint (the main result measured in a trial) for this trial. The clinical trial team will continue to monitor the safety of treatments – by checking the number and type of serious side effects and other certain side effects such as liver, kidney, heart, eye and immune problems. The number of treatments the participants receive in this trial will also be measured.

4. Who can take part in this clinical trial?

People can take part in this trial if they have cancer and have benefitted from the clinical trial treatment given in the parent trial. People may not be able to take part in this trial

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if they have stopped the clinical trial treatment in the parent trial for more than a certain amount of time or if they have been given certain other treatments for cancer since treatment in the parent trial stopped. People will also not be able to take part if the clinical trial treatment caused serious side effects that have not gone away or if the clinical trial treatment becomes available to them through routine healthcare outside of a clinical trial, if they are pregnant or breastfeeding, or are planning to become pregnant during the trial.

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

Everyone who joins this clinical trial will continue to be given the clinical trial treatment they received previously in a Genentech, Inc. and/or F. Hoffmann-La Roche Ltd-sponsored parent clinical trial. The treatment will be given in the same way as in the parent trial (for example, as an injection under the skin, an infusion into the vein, or as a tablet to be swallowed). This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

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. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate 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. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial treatments

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the treatments used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Participants will be told about the known side effects of clinical trial treatments and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of how the treatment will be given – for example, injections under the skin (subcutaneous injections), infusions into a vein (intravenous infusions), or swallowing tablets.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

Inclusion Criteria:

- Eligible for continuing atezolizumab-based therapy at the time of roll-over from the parent study, as per the parent study protocol or
- Eligible for continuing the comparator agent(s) in a Genentech- or Roche-sponsored study as per the parent study protocol, with no access to commercially available comparator agent
- Time between the last dose of treatment received in parent study and first dose in extension study is no longer than the interruption period allowed in the parent study. First dose of study treatment in this extension study will be received within 7 days of the treatment interruption window allowed by the parent study
- Continue to benefit from atezolizumab-based study treatment or from the comparator at the time of roll-over from the parent study as assessed by the investigator
- Negative serum pregnancy test within 7 days prior to start of study treatment in women of childbearing potential
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent or use contraceptive measures, and agreement to refrain from donating sperm

Exclusion Criteria:

- Meet any of the study treatment discontinuation criteria specified in the parent study at the time of enrollment in this extension study
- Study treatment or comparator agent is commercially marketed in the patient's country for the patient-specific disease and is accessible to the patient
- Treatment with any anti-cancer treatment during the time between last treatment in the parent study and the first dose of study treatment in this extension study
- Permanent discontinuation of atezolizumab for any reason during the parent study or during the time between last treatment in the parent study and the first dose of study treatment in this extension study (if applicable). Exception: Participants who permanently discontinued atezolizumab from parent studies that permit participants to continue treatment with the combination agent(s) alone after permanently discontinuing atezolizumab are eligible to enroll in this study.
- Ongoing serious adverse event(s) that has not resolved to baseline level or Grade #1 from the parent study or during the time between the last treatment in the parent study and the first dose of study treatment in this extension study
- Any condition that, in the opinion of the investigator, would interfere with the interpretation of patient safety or place the patient at high risk for treatment-related complications
- Concurrent participation in any therapeutic clinical trial (other than the parent study)
- Pregnant or lactating, or intending to become pregnant during this extension study and for the period after the last dose of study treatment specified in the designated referenced safety information (RSI)