

Cancer

A clinical trial to continue to provide treatments to participants who benefitted from them in an atezolizumab-based trial sponsored by Genentech Inc. and/or 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
Recruiting

Trial Runs In
14 Countries

Trial Identifier
NCT03768063 2018-003352-20
BO40729

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 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 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

NCT03768063 2018-003352-20 BO40729
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.

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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 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

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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.