ForPatients
*by Roche*

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 and continue to observe their overall survival status

A Study in Participants Previously Enrolled in a Genentech- and/or F. Hoffmann-La Roche Ltd-Sponsored Atezolizumab Study (IMbrella A)

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 32 Countries | NCT03148418 2016-005189-75 2023-506186-57-00 BO39633 |

*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:*

An Open-Label, Multicenter Extension and Long-Term Observational Study in Patients Previously Enrolled in a Genentech- and/or F. Hoffmann-La Roche Ltd-Sponsored Atezolizumab Study

## *Trial Summary:*

This is an open-label, multicenter, non-randomized extension and long-term observational study. Participants receiving atezolizumab monotherapy or atezolizumab combined with other agent(s) or comparator agent(s) in a Genentech or Roche-sponsored study (the parent study) and who continue to receive study treatment at the time of the parent-study closure and do not have access to the study treatment locally are eligible for continued treatment in the extension study. Dosing regimen for a given participant and indication will be the same or equivalent to the respective parent study protocol. Study treatment in the extension study can continue until disease progression or beyond if the patient continues to derive clinical benefit as judged by the investigator and if allowed by the parent study or local prescribing information until death; withdrawal of study consent; unacceptable toxicity; pregnancy; patient non-compliance; or study termination by the Sponsor, whichever occurs first.

| Hoffmann-La Roche | Phase 3 |
|---|---|
| Sponsor | Phase |

**NCT03148418 2016-005189-75 2023-506186-57-00 BO39633**
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## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | | No |

### 1. Why is the IMbrella A 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 trials) 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 A clinical trial work?

People can take part in this trial if they have cancer and were previously treated in an atezolizumabbased 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. Additionally, patients from study IMpower 133 are followed up for overall survival.

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 A 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. Participants from parent study IMpower 133 are being followed up for overall survival even after discontinuing from treatment.

**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 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. Patients, who discontinued an atezolizumab-based therapy in the IMpower133 parent study and are in survival follow-up at the time of IMpower133 parent study closure can continue survival follow-up (regardless whether they are receiving commercial Atezolizumab or not) in this study.

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

Patients who join 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:*

Specific criteria for patients who continue treatment as well as safety and survival follow-up in the extension study (and survival follow up for pattients who roll over from IMpower133):

- Eligible for continuing or crossing over to atezolizumab-based therapy at the time of the parent-study closure as per the parent study or eligible for continuing the comparator agent(s) in a Genentech- or Roche-sponsored study at the time of the parent-study closure as per the parent study, with no access to commercially available comparator agent
- First dose of study treatment in the 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 parent-study closure as assessed by the investigator
- Negative serum pregnancy test within 7 days prior to start of study treatment in women of childbearing potential

Specific criteria for patients from the IMpower133 parent study only who do not continue treatment in the extension study and/or receive commercially available atezolizumab (Tecentriq) outside this extension study and continue safety and survival follow-up only in the extension study:

- Discontinuation of atezolizumab-based therapy in the IMpower133 parent study and in survival follow-up at the time of IMpower133 parent study closure, or eligible for continuing or crossing over to atezolizumab-based therapy as per the IMpower133 parent protocol and have access to commercially available atezolizumab (Tecentriq) outside this extension study at the time of the IMpower133 parent-study closure

## *Exclusion Criteria:*

Specific criteria for patients who continue treatment as well as safety and survival follow-up in the extension study:

- Meet of any of the study treatment discontinuation criteria specified in the parent study at the time of enrollment in the extension study
- Study treatment is commercially marketed in the patient's country for the patient specific disease and is accessible to the patient
- Time between the last dose of treatment received in parent study and first dose in extension study is longer than the interruption period (± 7 days) allowed in the parent study
- Treatment with any anti-cancer treatment (other than treatment permitted in the parent study) during the time between last treatment in the parent study and the first dose of study treatment in the 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 the extension study (if applicable)
- Any unresolved or irreversible toxicities during the parent study that required permanent discontinuation of study treatment, in accordance to the parent study or local prescribing information
- Ongoing SAE(s) that has not resolved to baseline level or Grade less than or equal to (<=) 1 from the parent study or during the time between last treatment in the parent study and the first dose of study treatment in the extension study
- Any serious uncontrolled concomitant disease that would contraindicate the use of study treatment at the time of the extension study or that would place the participant at high risk for treatment-related complications
- Concurrent participation in any therapeutic clinical trial (other than the parent study)

Specific criteria for patients who do not continue treatment in the extension study and/or receive commercially available atezolizumab (Tecentriq) outside this extension study and continue safety and survival follow-up only in the extension study:

- Discontinuation of comparator in parent study and in survival follow-up at the time of parent study closure