ForPatients
by Roche

Cancer

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 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 BO39633
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

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