

NeoplasmsTumorSolid Tumors

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

Trial Status
Active, not recruiting

Trial Runs In
1 Country

Trial Identifier
NCT05112965 YO42713

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

Trial Summary:

This is an open-label, multicenter, non-randomized extension 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), who are eligible to continue treatment and do not have access to the study treatment locally, continue to receive study treatment in this extension study.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05112965 YO42713
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Eligible for continuing or crossing over to atezolizumab-based therapy at the time of rollover from the parent study, as per the parent study protocol, or

ForPatients

by Roche

- 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
- 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 rollover 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 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 serious adverse events that have 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 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 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 the extension study