ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

A Study to Investigate the Safety and Efficacy of Atezolizumab in Previously-Treated Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03922997 ML40471

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, Singe Arm, Multicenter Study to Investigate the Safety and Efficacy of Atezolizumab (Tecentriq) in Previously-Treated Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Summary:

This is a phase III, single-arm, multicenter study of the long-term safety and efficacy of atezolizumab treatment in patients with Stage IIIb or Stage IV non-small cell lung cancer (NSCLC) who have progressed following standard systemic chemotherapy (including if given in combination with anti-PD-1 therapy or after anti-PD-1 as monotherapy).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03922997 ML40471
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically documented Stage IIIb or Stage IV NSCLC that has progressed following standard systemic chemotherapy (including if given in combination with anti-PD-1 therapy or after anti-PD-1 as monotherapy). Patients with a previously detected EGFR mutation or ALK fusion oncogene will be excluded from this study. Overall, patients should not have received more than two

lines of systemic chemotherapy. Patients who have discontinued first-line or second-line systemic chemotherapy, targeted therapy, or anti-PD-1 therapy due to intolerance are also eligible.
- The last dose of prior systemic anticancer therapy must have been administered # 21 days prior to the first study treatment.
- The last dose of prior anti-PD-1 therapy must have been administered
- Measurable disease, as defined by Response Evaluation Criteria for Solid Tumors, Version 1.1 (RECIST v1.1)
- Patients with asymptomatic CNS metastases (treated or untreated), as determined by CT or MRI evaluation during screening and prior radiographic evaluation, are eligible
- ECOG performance status 0, 1, or 2
- Life expectancy # 12 weeks
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab
- Patients must have recovered from all acute toxicities from previous therapy, excluding alopecia and toxicities related to prior anti-PD-1-therapy

Exclusion Criteria:

- Patients with EGFR mutation or ALK fusion oncogene
- Symptomatic CNS metastases
- Spinal cord compression not definitively treated with surgery and/or radiation or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for # 2 weeks prior to the first study treatment
- Leptomeningeal disease
- Uncontrolled pericardial effusion or ascites requiring recurrent drainage procedures
- Pregnant or lactating, or intending to become pregnant during the study
- Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol, including significant liver disease
- Significant cardiovascular disease
- Significant renal disorder requiring dialysis or indication for renal transplant
- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days prior to study treatment initiation
- Major surgical procedure within 4 weeks prior to study treatment initiation or anticipation of need for a major surgical procedure during the course of the study other than for diagnosis
- Prior allogeneic stem cell or solid organ transplantation