ForPatients
*by Roche*

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

# A Study of Atezolizumab Compared With Platinum Doublet Chemotherapy for PD-L1 Highly Expressed, Chemotherapy-Naïve Patients With Stage IV Non-Squamous or Squamous Non-Small Cell Lung Cancer

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 1 Country | NCT05047250 ML42606 |

*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:*

A Phase III, Single-Arm Multicenter Study of Atezolizumab (Anti-PD-L1 Antibody) in High PD-L1 Expression, Chemotherapy-Naïve Patients With Stage IV Non-Squamous or Squamous Non-Small Cell Lung Cancer

## *Trial Summary:*

This is a Phase III, single arm, multicenter study designed to evaluate the efficacy and safety of atezolizumab in high PD-L1 expression, chemotherapy-naïve, without a sensitizing EGFR mutation or ALK translocation patients with stage IV non-squamous or squamous NSCLC.

**Hoffmann-La Roche**
Sponsor

**Phase 3**
Phase

**NCT05047250 ML42606**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- ECOG performance status of 0 or 1.
- Histologically or cytologically confirmed, Stage IV non-squamous or squamous NSCLC.

- No prior treatment for Stage IV non-squamous or squamous NSCLC.
- Patients who have received prior neo-adjuvant, adjuvant chemotherapy, radiotherapy, or chemo-radiotherapy with curative intent for non-metastatic disease must have experienced a treatment free interval of at least 6 months from enrollment since the last chemotherapy, radiotherapy, or chemo-radiotherapy cycle.
- Tumor TC3 or IC3, as determined by SP142 performed by a central laboratory on previously obtained archival tumor tissue or tissue obtained from a biopsy at screening.
- Measurable disease, as defined by RECIST v1.1.
- Adequate hematologic and end-organ function.
- Life expectancy #3 months.
- For women of childbearing potential: agreement to remain abstinent or use contraception, and agreement to refrain from donating.

## *Exclusion Criteria:*

- Known sensitizing mutation in the EGFR gene or ALK fusion oncogene.
- Symptomatic, untreated, or actively progressing 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 enrollment.
- Current leptomeningeal disease.
- Uncontrolled tumor-related pain.
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures.
- Uncontrolled or symptomatic hypercalcemia.
- Malignancies other than NSCLC within 5 years prior to enrollment, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome.
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within at least 5 months after the last dose of atezolizumab.
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins.
- Known allergy or hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation.
- Active or history of autoimmune disease or immune deficiency.
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan.
- Positive human immunodeficiency virus (HIV) test result at screening.
- Patients with active hepatitis B or active hepatitis C at screening.
- Active tuberculosis.
- Severe infections within 4 weeks prior to randomization, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia.
- Significant cardiovascular disease.