ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab Compared With Docetaxel in Non-Small Cell Lung Cancer (NSCLC) After Failure With Platinum-Containing Chemotherapy

Trial Status	Trial Runs In	Trial Identifier
Completed	5 Countries	NCT02813785 YO29232

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, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared With Docetaxel in Patients With Non-Small Cell Lung Cancer After Failure With Platinum-Containing Chemotherapy

Trial Summary:

This Phase III, multicenter, open-label, randomized, controlled study is designed to evaluate the efficacy and safety of the anti-programmed death-ligand 1 (PD-L1) antibody atezolizumab compared with docetaxel in participants with locally advanced or metastatic NSCLC who have progressed during or following a platinum-containing regimen. Treatment may continue until disease progression, loss of clinical benefit, or unacceptable toxicity.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02813785 YO29232
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically documented, locally advanced or metastatic NSCLC

- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens available or at least 12 unstained, freshly cut serial sections with associated pathology report that are evaluable for PD-L1 expression and epidermal growth factor receptor (EGFR) mutation status prior to enrollment, except for known sensitizing EGFR mutations in which case 10 unstained slides are required and there is no need for central testing of EGFR mutation status
- Disease progression during or following treatment with a prior platinum-containing regimen for locally advanced, unresectable, inoperable, or metastatic NSCLC, or disease recurrence within 6 months of treatment with a platinum-based adjuvant and/or neoadjuvant regimen or combined modality with curative intent
- Measurable disease per RECIST v1.1
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy greater than or equal to (>/=) 12 weeks
- Adequate hematologic and end organ function
- Agreement to remain abstinent or use contraceptive methods among women of childbearing potential or male partners of women of childbearing potential
- Recovery from all acute toxicities from previous therapy

Exclusion Criteria:

- Active or untreated central nervous system (CNS) metastases
- Spinal cord compression not definitively treated or not clinically stable
- Leptomeningeal disease
- Uncontrolled pleural or pericardial effusions or ascites requiring recurrent drainage
- Uncontrolled tumor-related pain
- Uncontrolled hypercalcemia
- Malignancies other than NSCLC within 5 years prior to randomization, except for those curatively treated with negligible risk of metastasis or death
- Pregnant or lactating women
- Significant cardiovascular, pulmonary, or autoimmune disease
- Severe infection or major surgery within 4 weeks, or antibiotic treatment within 2 weeks prior to randomization
- Prior treatment with or hypersensitivity to study drug(s) or related compounds
- Inability to discontinue strong cytochrome P450 (CYP) 3A4 inhibitors
- Prior allogeneic bone marrow or solid organ transplant
- Known PD-L1-negative expression status
- Positive human immunodeficiency virus (HIV) or active hepatitis B or C
- Receipt of a live attenuated vaccine within 4 weeks prior to randomization
- Treatment with systemic immunomodulators within 4 weeks or five half-lives (whichever is shorter) prior to randomization
- Treatment with systemic corticosteroids within 2 weeks prior to randomization