ForPatients
by Roche

Non-squamous non-small cell lung cancerNon-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab Compared With Docetaxel in Participants With Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum-Containing Therapy

Trial Status	Trial Runs In	Trial Identifier
Completed	31 Countries	NCT02008227 2013-003331-30 GO28915

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 global, multicenter, open-label, randomized, controlled study evaluated the efficacy and safety of atezolizumab (an anti-programmed death-ligand 1 [anti-PD-L1] antibody)compared with docetaxel in participants with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure with platinum-containing chemotherapy. Participants were randomized 1:1 to receive either docetaxel or atezolizumab. Treatment may continue as long as participants experienced clinical benefit as assessed by the investigator, i.e., in the absence of unacceptable toxicity or symptomatic deterioration attributed to disease progression.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02008227 2013-003331-30 GO28915
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

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Inclusion Criteria:

- Locally advanced or metastatic (Stage IIIB, Stage IV, or recurrent) NSCLC
- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens
- 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/neoadjuvant regimen or combined modality (e.g., chemoradiation) regimen with curative intent
- Measurable disease, as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

Exclusion Criteria:

- Known active or untreated central nervous system (CNS) metastases
- Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest computed tomography (CT) scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Active hepatitis B or hepatitis C
- Prior treatment with docetaxel
- Prior treatment with cluster of differentiation 137 (CD137) agonists, anti-cytotoxic-T-lymphocyte-associated antigen 4 (anti-CTLA4), anti-programmed death-1 (anti-PD-1), or anti-PD-L1 therapeutic antibody or pathway-targeting agents