ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab in Combination With Carboplatin + Paclitaxel or Carboplatin + Nab-Paclitaxel Compared With Carboplatin + Nab-Paclitaxel in Participants With Stage IV Squamous Non-Small Cell Lung Cancer (NSCLC) [IMpower131]

Trial Status	Trial Runs In	Trial Identifier
Completed	26 Countries	NCT02367794 2014-003208-59 GO29437

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 Evaluating the Efficacy and Safety of Atezolizumab (MPDL3280A, Anti-PD-L1 Antibody) in Combination With Carboplatin+Paclitaxel or Atezolizumab in Combination With Carboplatin+Nab-Paclitaxel Versus Carboplatin+Nab-Paclitaxel in Chemotherapy-Naive Patients With Stage IV Squamous Non-Small Cell Lung Cancer

Trial Summary:

This randomized, open-label study will evaluate the safety and efficacy of atezolizumab (MPDL3280A) in combination with carboplatin + paclitaxel or carboplatin + nab-paclitaxel compared with treatment with carboplatin + nab-paclitaxel in chemotherapy-naive participants with Stage IV squamous NSCLC.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02367794 2014-003208-59 GO29437
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

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- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Histologically or cytologically confirmed, treatment-naïve Stage IV squamous NSCLC
- Previously obtained archival tumor tissue or tissue obtained from biopsy at screening
- Measurable disease as defined by RECIST v1.1
- Adequate hematologic and end organ function

Exclusion Criteria:

- Active or untreated central nervous system (CNS) metastasis
- Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome
- Pregnant or lactating women
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest Computed Tomography (CT) scan, History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Positive test for Human Immunodeficiency Virus (HIV)
- Active hepatitis B or hepatitis C
- Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint blockade therapies, anti-programmed death-1 (anti-PD-1), and anti-PD-L1 therapeutic antibody
- Severe infection within 4 weeks prior to randomization
- Significant history of cardiovascular disease

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