ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

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

Trial Status	Trial Runs In	Trial Identifier
Completed	8 Countries	NCT02367781 2014-003206-32 GO29537

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

Trial Summary:

This randomized Phase III, multicenter, open-label study designed to evaluate the safety and efficacy of atezolizumab (an engineered anti-programmed death-ligand 1 [PD-L1] antibody) in combination with carboplatin+nab-paclitaxel compared with treatment with carboplatin+nab-paclitaxel in chemotherapy-naive participants with Stage IV non-squamous NSCLC. Participants were randomized in a 2:1 ratio to Arm A (Atezolizumab +Nab-Paclitaxel+Carboplatin) or Arm B (Nab-Paclitaxel+Carboplatin).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group performance status of 0 or 1
- Histologically or cytologically confirmed, Stage IV non-squamous NSCLC
- Participants with no prior treatment for Stage IV non-squamous NSCLC
- Previously obtained archival tumor tissue or tissue obtained from fresh biopsy at screening
- Measurable disease, as defined by RECIST v1.1
- Adequate hematologic and end organ function

Exclusion Criteria:

Cancer-Specific Exclusions:

- Active or untreated central nervous system metastases
- 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

General Medical Exclusions:

- 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 scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Positive test for human immunodeficiency virus
- Active hepatitis B or hepatitis C
- Severe infection within 4 weeks prior to randomization
- Significant cardiovascular disease
- Illness or condition that interferes with the participant's capacity to understand, follow and/or comply with study procedures

Exclusion Criteria Related to Medications:

- Prior treatment with cluster of differentiation 137 agonists or immune checkpoint blockade therapies, anti-programmed death-1, and anti-PD-L1 therapeutic antibodies