ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab in Combination With Carboplatin or Cisplatin + Pemetrexed Compared With Carboplatin or Cisplatin + Pemetrexed in Participants Who Are Chemotherapy-Naive and Have Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (IMpower 132)

Trial Status	Trial Runs In	Trial Identifier
Completed	27 Countries	NCT02657434 2015-003605-42 GO29438

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, Randomized Study of Atezolizumab (MPDL3280A, Anti-Pd-L1 Antibody) in Combination With Carboplatin or Cisplatin + Pemetrexed Compared With Carboplatin or Cisplatin + Pemetrexed in Patients Who Are Chemotherapy-Naive and Have Stage IV Non-Squamous Non-Small Cell Lung Cancer

Trial Summary:

This is a randomized, Phase III, multicenter, open-label study designed to evaluate the safety and efficacy of atezolizumab in combination with cisplatin or carboplatin + pemetrexed compared with treatment with cisplatin or carboplatin + pemetrexed in participants who are chemotherapy-naive and have Stage IV non-squamous NSCLC. Eligible participants will be randomized by a 1:1 ratio into 2 groups: Arm A (Atezolizumab + Carboplatin or Cisplatin + Pemetrexed) and Arm B (Carboplatin or Cisplatin + Pemetrexed). The study will be conducted in two phases: Induction Phase and Maintenance Phase.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02657434 2015-003605-42 GO29438
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Histologically or cytologically confirmed, Stage IV non-squamous NSCLC. Participants with tumors of mixed non-small cell histology (i.e., squamous and non-squamous) are eligible if the major histological component appears to be non-squamous
- No prior treatment for Stage IV non-squamous NSCLC. Participants with a sensitizing mutation in the epidermal growth factor receptor (EGFR) gene or with an anaplastic lymphoma kinase (ALK) fusion oncogene are excluded. Participants with unknown EGFR and ALK status require test results at screening from a local or central laboratory
- Participants who have received prior neo-adjuvant, radiotherapy, adjuvant chemotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a treatment-free interval of at least 6 months from randomization since the last dose of chemotherapy and/or radiotherapy
- Participants should submit a pre-treatment tumor tissue sample if available before or within 4 weeks after enrollment. If tumor tissue is not available, participants are still eligible
- For participants enrolled in the extended China enrollment phase: current resident of mainland China, Hong Kong, or Taiwan and of Chinese ancestry
- Measurable disease, as defined by RECIST v1.1
- Adequate hematologic and end organ function
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods that result in a failure rate of less than (<) 1 percent (%) per year during the treatment period and for at least 5 months after the last dose of atezolizumab or 6 months after the last dose of cisplatin
- For men: agreement to remain abstinent or use contraceptive measures and agreement to refrain from donating sperm

Exclusion Criteria:

Cancer-Specific Exclusions

- Participants with a sensitizing mutation in the EGFR gene or an ALK fusion oncogene
- Active or untreated central nervous system (CNS) metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening and prior radiographic assessments
- 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 greater than or equal to (>= 2) weeks prior to randomization
- Leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled or symptomatic hypercalcemia (greater than [>] 1.5 millimole/Liter ionized calcium or calcium >12 milligrams/deciliter or corrected serum calcium >upper limit of normal)
- Malignancies other than NSCLC within 5 years prior to randomization
- Known tumor programmed death-ligand 1 (PD-L1) expression status from other clinical studies (e.g., participants whose PD-L1 expression status was determined during screening for entry into a study with anti-PD-1 or anti-PD L1 antibodies but were not eligible are excluded)

General Medical Exclusions:

- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- History of certain autoimmune disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis
- All participants will be tested for human immunodeficiency virus (HIV) prior to the inclusion into the study and HIV-positive participants will be excluded from the clinical study
- Severe infections within 4 weeks prior to randomization
- Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction or cerebrovascular accident within 3 months prior to randomization, unstable arrhythmias, or unstable angina
- Illness or condition that may interfere with a participant's capacity to understand, follow, and/or comply with study procedures

Exclusion Criteria Related to Medications and Chemotherapy:

- Prior treatment with EGFR inhibitors or ALK inhibitors
- Any approved anti-cancer therapy, including hormonal therapy within 21 days prior to initiation of study treatment
- Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint blockade therapies, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks prior to randomization
- Treatment with systemic immunosuppressive medications

Exclusion Criteria Related to Chemotherapy:

- History of allergic reactions to cisplatin, carboplatin, or other platinum-containing compounds
- Participants with hearing impairment (cisplatin)
- Grade >=2 peripheral neuropathy as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.0 criteria (cisplatin)
- Creatinine clearance (CRCL) <60 milliliters/minute (mL/min) for cisplatin or <45 mL/min for carboplatin