

Câncer Pulmonar de Células Não Pequenas

Um estudo de atezolizumabe em combinação com carboplatina mais (+) paclitaxel com ou sem bevacizumabe comparado com carboplatina + paclitaxel + bevacizumabe em participantes com câncer de pulmão de células não pequenas (NSCLC) não escamoso em estágio IV

A Study of Atezolizumab in Combination With Carboplatin Plus (+) Paclitaxel With or Without Bevacizumab Compared With Carboplatin+Paclitaxel+Bevacizumab in Participants With Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

Trial Status
Concluído

Trial Runs In
28 Countries

Trial Identifier
NCT02366143 2014-003207-30
GO29436

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Phase III, Open-Label, Randomized Study of Atezolizumab (MPDL3280A, Anti-PD-L1 Antibody) in Combination With Carboplatin+Paclitaxel With or Without Bevacizumab Compared With Carboplatin + Paclitaxel + Bevacizumab in Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer

Trial Summary:

This randomized, open-label study evaluated the safety and efficacy of atezolizumab (an engineered anti-programmed death-ligand 1 [PD-L1] antibody) in combination with carboplatin+paclitaxel with or without bevacizumab compared with treatment with carboplatin+paclitaxel+bevacizumab in chemotherapy-naïve participants with Stage IV non-squamous NSCLC. Participants were randomized in a 1:1:1 ratio to Arm A (Atezolizumab+Carboplatin+Paclitaxel), Arm B (Atezolizumab+Carboplatin+Paclitaxel +Bevacizumab), or Arm C (Carboplatin+Paclitaxel+Bevacizumab).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02366143 2014-003207-30 GO29436
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group performance status 0 or 1
- Histologically or cytologically confirmed, Stage IV non-squamous NSCLC
- Participants with no prior treatment for Stage IV non-squamous NSCLC
- Known PD-L1 status as determined by immunohistochemistry assay performed on previously obtained archival tumor tissue or tissue obtained from a 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