ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab in Participants With Programmed Death - Ligand 1 (PD-L1) Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	19 Countries	NCT02031458 2013-003330-32 GO28754

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 II, Multicenter, Single-Arm Study OF Atezolizumab In Patients With PD-L1-Positive Locally Advanced Or Metastatic Non-Small Cell Lung Cancer

Trial Summary:

This multicenter, single-arm study will evaluate the efficacy and safety of Atezolizumab in participants with PD-L1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC). Participants will receive Atezolizumab 1200 milligrams (mg) intravenously every 3 weeks as long as participants are experiencing clinical benefit as assessed by the investigator, that is , in the absence of unacceptable toxicity or symptomatic deterioration attributed to disease progression.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT02031458 2013-003330-32 GO28754
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Adult participants greater than or equal to 18 years of age

- Locally advanced or metastatic (Stage IIIB, Stage IV, or recurrent) NSCLC
- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens
- PD-L1-positive tumor status as determined by an immunohistochemistry (IHC) assay based on PD-L1 expression on tumor infiltrating immune cells and/or tumor cells performed by a central laboratory
- Measurable disease, as defined by RECIST version 1.1
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

Exclusion Criteria:

- Any approved anti-cancer therapy, including chemotherapy, or hormonal therapy within 3 weeks prior to initiation of study treatment; the following exception are allowed:

Hormone-replacement therapy or oral contraceptives tyrosine-kinase inhibitors (TKIs) approved for treatment of NSCLC discontinued >7 days prior to Cycle 1, Day 1

- Central nervous system (CNS) disease, including treated brain metastases
- Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with negligible risk of metastases or death and treated with expected curative outcome
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis (including pneumonia), drug-induced pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening CT scan. History of radiation pneumonitis in the radiation field (fibrosis) id permitted
- Active hepatitis B or hepatitis C
- Human Immunodeficiency virus (HIV) positive
- Prior treatment with CD137 agonists, anti-CTLA4, anti-PD-1, or anti-PD-L1 therapeutic antibody or pathway-targeting agents