ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab Compared With Chemotherapy in Treatment Naïve Participants With Locally Advanced or Recurrent or Metastatic Non-Small Cell Lung Cancer Who Are Deemed Unsuitable For Platinum-Containing Therapy

Trial Status	Trial Runs In	Trial Identifier
Completed	24 Countries	NCT03191786 2015-004105-16 MO29872

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 to Investigate the Efficacy and Safety of Atezolizumab Compared With Chemotherapy in Patients With Treatment Naïve Advanced or Recurrent (Stage IIIb Not Amenable for Multimodality Treatment) or Metastatic (Stage IV) Non-Small Cell Lung Cancer Who Are Deemed Unsuitable for Platinum-Containing Therapy

Trial Summary:

This Phase III, global, multicenter, open-label, randomized, controlled study will evaluate the efficacy and safety of atezolizumab (an anti-programmed death-ligand 1 [anti-PD-L1] antibody) compared with a single agent chemotherapy regimen by investigator choice (vinorelbine or gemcitabine) in treatment-naïve participants with locally advanced or metastatic non-small cell lung cancer (NSCLC) who are deemed unsuitable for any platinum-doublet chemotherapy due to poor performance status (Eastern Cooperative Oncology Group [ECOG] performance status of 2-3).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03191786 2015-004105-16 MO29872
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

© 2022 F. Hoffmann-La Roche Ltd

Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC as per the American Joint Committee on Cancer (AJCC) 7th edition
- No sensitizing epidermal growth factor receptor (EGFR) mutation (L858R or exon 19 deletions) or anaplastic lymphoma kinase (ALK) fusion oncogene detected
- No prior systemic treatment for advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC as per the AJCC 7th edition
- Life expectancy greater than or equal to (>/=) 8 weeks
- Deemed unsuitable by the investigator for any platinum-doublet chemotherapy due to poor performance status (ECOG performance status of 2-3). However, participants >= 70 years of age who have an ECOG PS of 0 or 1 may be included due to: a) substantial comorbidities; b) contraindication(s) for any platinum-doublet chemotherapy
- Representative formalin-fixed paraffin-embedded (FPPE) tumor tissue block obtained during course of disease (archival tissue) or at screening
- Participants with treated, asymptomatic central nervous system (CNS) metastases are eligible, provided they meet all of the following criteria: Measurable disease outside CNS; Only supratentorial and cerebellar metastases allowed; No ongoing requirement for corticosteroids as therapy for CNS disease; No stereotactic radiation within 7 days or whole-brain radiation within 14 days prior to randomization; No evidence of interim progression between the completion of CNS-directed therapy and the screening radiographic study
- Adequate hematologic and end organ function
- Female participants of childbearing potential randomized to the atezolizumab treatment arm agree to use protocol defined methods of contraception

Exclusion Criteria:

Cancer-Specific Exclusion Criteria:

- Participants younger than 70 years who have an ECOG performance status of 0 or 1
- Active or untreated CNS metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation of the brain during screening and prior radiographic assessments
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- Uncontrolled or symptomatic hyerpcalcemia (ionized calcium > 1.5 mmol/L or calcium >12 mg/dL or corrected serum calcium >ULN)
- History of other malignancy within 5 years prior to screening, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome
- National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.0 (v4.0) Grade 3 or higher toxicities due to any prior therapy (example [e.g.], radiotherapy) (excluding alopecia), which have not shown improvement and are strictly considered to interfere with current study medication
- Participants who have received prior neo-adjuvant, adjuvant chemotherapy, radiotherapy, 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 chemotherapy, radiotherapy, or chemoradiotherapy

General Medical Exclusion Criteria:

© 2022 F. Hoffmann-La Roche Ltd

- History of autoimmune disease except autoimmune-related hypothyroidism and controlled Type I diabetes mellitus
- History of idiopathic pulmonary fibrosis (IPF), organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis
- Known positivity for human immunodeficiency virus (HIV)
- Known active hepatitis B or hepatitis C
- Active tuberculosis
- Severe infections within 4 weeks prior to randomization
- Significant cardiovascular disease, such as New York Heart Association (NYHA) cardiac disease (Class II or greater), myocardial infarction within 3 months prior to randomization, unstable arrhythmias, or unstable angina
- Major surgical procedure other than for diagnosis within 4 weeks prior to randomization or anticipation of need for a major surgical procedure during the course of the study
- Prior allogeneic bone marrow transplantation or solid organ transplant
- Participants with an illness or condition that may interfere with capacity or compliance with the study protocol, as per investigator's judgment
- Treatment with any other investigational agent or participation in another clinical study with therapeutic intent within 28 days prior to randomization

Exclusion Criteria Related to Atezolizumab:

- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- Oral or IV antibiotic treatment
- Administration of a live, attenuated vaccine within 4 weeks before randomization or anticipation that such a live attenuated vaccine will be required during the study
- 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 antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to randomization
- Treatment with systemic corticosteroids or other immunosuppressive medications
- Participants not willing to stop treatment with traditional herbal medicines

Exclusion Criteria Related to Chemotherapy:

- Known sensitivity and contraindications to the 2 comparative chemotherapy agents (that is [i.e.] vinorelbine, oral or intravenous, and gemcitabine, intravenous)

© 2022 F. Hoffmann-La Roche Ltd