ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of MTIG7192A in Combination With Atezolizumab in Chemotherapy-Naïve Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	6 Countries	NCT03563716 2018-000280-81 GO40290

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, Randomized, Blinded, Placebo-Controlled Study of Tiragolumab, An Anti-TIGIT Antibody, In Combination With Atezolizumab In Chemotherapy-Naïve Patients With Locally Advanced Or Metastatic Non-Small Cell Lung Cancer

Trial Summary:

This study will evaluate the safety and efficacy of tiragolumab plus atezolizumab compared with placebo plus atezolizumab in chemotherapy-naive patients with locally advanced unresectable or metastatic PD-L1-selected non-small cell lung cancer (NSCLC), excluding patients with a sensitizing EGFR mutation or ALK translocation.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03563716 2018-000280-81 GO40290
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- ECOG Performance Status of 0 or 1
- Histologically or cytologically documented locally advanced unresectable NSCLC, recurrent, or metastatic NSCLC of either squamous or non-squamous histology

- No prior systemic treatment for locally advanced unresectable or metastatic NSCLC
- Tumor PD-L1 expression
- Measurable disease, as defined by RECIST v1.1
- Life expectancy >=12 weeks
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm

Exclusion Criteria:

Cancer-Specific Exclusions:

- Patients with NSCLC known to have a sensitizing mutation in the EGFR gene or an ALK fusion oncogene
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Spinal cord compression not definitively treated with surgery and/or radiation, and/or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for >=2 weeks prior to screening
- History of leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled tumor-related pain
- Uncontrolled hypercalcemia or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
- Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death and/or treated with expected curative outcome

General Medical Exclusions:

- Pregnant and lactating women
- Significant cardiovascular disease
- Severe infections within 4 weeks prior to randomization
- Major surgical procedure other than for diagnosis within 4 weeks prior to randomization

Treatment-Specific Exclusions:

- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins; known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- History of autoimmune disease
- Prior allogeneic bone marrow transplantation or solid organ transplantation
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan
- Positive test for human immunodeficiency virus (HIV) and/or active hepatitis B or hepatitis C or active tuberculosis
- Administration of a live, attenuated vaccine within 4 weeks prior to randomization