ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of Atezolizumab in Combination With Bevacizumab in Patients With EGFR Mutation Positive Stage IIIB/IV Non-Squamous Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04426825 ML41256

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 Single Arm, Phase II Study of Atezolizumab (MPDL3280A, Anti-PD-L1 Antibody) in Combination With Bevacizumab in Patients With EGFR Mutation Positive Stage IIIB-IV Non-Squamous Non-Small Cell Lung Cancer Pretreated With Epidermal Growth Factor Receptor Tyrosine-Kinase Inhibitors

Trial Summary:

This is an open-label, single-arm, phase II, multicenter study designed to evaluated the efficacy and safety of atezolizumab in combination with bevacizumab in PD-L1-selected patients with Stage IIIB-IV Non-Squamous NSCLC harbored EGFR mutation after EGFR TKI therapy.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04426825 ML41256
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Life expectancy # 10 months
- Histologically or cytologically confirmed stage IIIB, IIIC, or IV non-squamous NSCLC. Patients with tumors of mixed histology are eligible if the major histological component appears to be non-squamous.

- No prior treatment for Stage IIIB, IIIC, or IV non-squamous NSCLC, with the following exceptions:

Patients with a sensitizing mutation in the EGFR gene must have experienced disease progression or were intolerant to treatment with one or more EGFR TKIs. Patients who have progressed on or were intolerant to first-line osimertinib or other thirdgeneration EGFR TKIs are eligible.

Patients who have progressed on or were intolerant to first- or second-generation EGFR TKIs, and who have no evidence of the EGFR T790M mutation after TKI therapy are eligible.

Patients who have progressed on or were intolerant to first- or second-generation EGFR TKIs and who have evidence of the T790M mutation must have also progressed on or were intolerant to osimertinib to be eligible.

- TKIs approved for treatment of NSCLC discontinued >7 days prior to enrollment.
- Measurable disease per RECIST v1.1. PD-L1 expression of #1% as documented through central testing of a representative tumor tissue specimen either from previously obtained archival tumor tissue or tissue obtained from a biopsy at screening
- ECOG Performance Status of 0-1
- Adequate hematologic and end-organ function
- Negative HIV test at screening
- Negative hepatitis B surface antigen (HBsAg) test at screening
- Negative total hepatitis B core antibody (HBcAb) test at screening, or positive total HBcAb test followed by a negative hepatitis B virus (HBV) DNA test at screening. The HBV DNA test will be performed only for patients who have a positive total HBcAb test.
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening. The HCV RNA test will be performed only for patients who have a positive HCV antibody test.
- 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 a condom, and agreement to refrain from donating sperm.

Exclusion Criteria:

- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases as determined by CT or MRI evaluation during screening and prior radiographic assessments
- History of leptomeningeal disease
- Prior chemotherapy or other systemic therapy for stage IIIB, IIIC, or IV disease
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Active tuberculosis
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- History of malignancy other than NSCLC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Prior allogeneic stem cell or solid organ transplantation

- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during atezolizumab treatment or within 5 months after the final dose of atezolizumab
- Current treatment with anti-viral therapy for HBV
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, 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 longer) prior to initiation of study treatment
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to Chinese hamster ovary cell products or to any component of the atezolizumab or bevacizumab formulations
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab, 6 months after the final dose of bevacizumab
- Prior history of hypertensive crisis or hypertensive encephalopathy
- Significant vascular disease within 6 months prior to initiation of study treatment
- History of Grade # 2 hemoptysis within 1 month prior to enrollment
- Evidence of bleeding diathesis or coagulopathy. Current or recent use of aspirin, clopidogrel or treatment with dipyramidole, ticlopidine, or cilostazol
- Current use of full-dose oral or parenteral anticoagulants or thrombolytic agents for therapeutic purposes that has not been stable for > 2 weeks prior to enrollment
- History of stroke or transient ischemic attack within 6 months prior to enrollment
- Core biopsy or other minor surgical procedure, excluding placement of a vascular access device, within 7 days prior to the first dose of bevacizumab
- History of abdominal or tracheosphageal fistula or gastrointestinal perforation within 6 months prior to enrollment
- History of intra-abdominal inflammatory process within 6 months prior to initiation of study treatment, including but not limited to active peptic ulcer disease, diverticulitis,or colitis
- Clinical signs of gastrointestinal obstruction or requirement for routine parenteral hydration, parenteral nutrition, or tube feeding
- Evidence of abdominal free air not explained by paracentesis or recent surgical procedure
- Proteinuria
- Clear tumor infiltration into the thoracic great vessels is seen on imaging
- Clear cavitation of pulmonary lesions is seen on imaging