ForPatients
by Roche

Non Small Cell Lung CarcinomaLung Cancer

A Study of Bevacizumab, Carboplatin, and Paclitaxel or Pemetrexed With or Without Atezolizumab in Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer (IMpower151)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04194203 YO30157

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, Randomized, Double-Blind Study of Bevacizumab, Carboplatin, and Paclitaxel or Pemetrexed With or Without Atezolizumab in Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer (IMpower151)

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab when given in combination with bevacizumab, investigator's choice of either paclitaxel or pemetrexed, and carboplatin compared with placebo given in combination with bevacizumab, paclitaxel or pemetrexed, and carboplatin in patients with chemotherapy-naive, Stage IV non-squamous Non-Small Cell Lung Cancer (NSCLC). The study will be conducted in two phases: Induction Phase and Maintenance Phase.

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

NCT04194203 YO30157
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed Stage IV non-squamous NSCLC

- No prior treatment for Stage IV non-squamous NSCLC, with the following exceptions: (1) Patients with a sensitizing mutation in the EGFR gene must have experienced disease progression (during or after treatment) or were intolerant to treatment with one or more EGFR TKIs, such as erlotinib, gefitinib, afatinib, dacomitinib, and osimertinib, or another EGFR TKI appropriate for the treatment of EGFR-mutant NSCLC. Patients who have progressed on or were intolerant to first-line osimertinib or other third-generation EGFR TKIs are eligible. Patients who have progressed on or were intolerant to first- or second-generation EGFR TKIs, such as erlotinib, gefitinib, afatinib, dacomitinib, and who have no evidence of the EGFR T790M mutation in the tumor tissue 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 in their tumor tissue must have also progressed on or were intolerant to osimertinib to be eligible. (2) Patients with an ALK gene rearrangement must have experienced disease progression or were intolerant to treatment with one or more ALK inhibitors, such as crizotinib, alectinib, ceritinib, brigatinib, ensartinib and lorlatinib that are appropriate for the treatment of NSCLC that has an ALK gene rearrangement.
- Availability of a representative tumor specimen that is suitable for the determination of PD-L1 status, as well as the presence of EGFR mutations and ALK gene rearrangements, via central testing.
- Treatment-free interval of at least 6 months from randomization since the last chemotherapy, radiotherapy, or chemoradiotherapy treatment for patients who have received prior neoadjuvant and/or adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease
- Measurable disease, as defined by RECIST v1.1
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Life expectancy >=3 months
- 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
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening
- 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 CNS metastases
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- Uncontrolled or symptomatic hypercalcemia
- 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
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the course of the study
- 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
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications
- 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 any approved anti-cancer therapy or investigational therapy within 28 days prior to initiation of study treatment, except for treatment with TKI that should be discontinued for at least 8 days or for approximately 5 x half-life, whichever is the longer, before the first dose 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
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab or 6 months after the final dose of bevacizumab, carboplatin, pemetrexed, and paclitaxel