ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

A clinical trial to compare atezolizumab and cabozantinib with docetaxel in people with metastatic non-small cell lung cancer (after previous treatment with a checkpoint inhibitor and platinum-containing chemotherapy has not worked).

Study of Atezolizumab in Combination With Cabozantinib Versus Docetaxel in Patients With Metastatic Non-Small Cell Lung Cancer Previously Treated With an Anti-PD-L1/PD-1 Antibody and Platinum-Containing Chemotherapy

Trial Status	Trial Runs In	Trial Identifier
Completed	15 Countries	NCT04471428 GO41892

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, Multicenter, Randomized, Open-Label, Controlled Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Atezolizumab Given in Combination With Cabozantinib Versus Docetaxel Monotherapy in Patients With Metastatic Non-Small Lung Cancer Previously Treated With an Anti-PD-L1/PD-1 Antibody and Platinum-Containing Chemotherapy

Trial Summary:

This is a Phase III, multicenter, randomized, open-label study designed to evaluate the efficacy, safety, and pharmacokinetics of atezolizumab given in combination with cabozantinib compared with docetaxel monotherapy in patients with metastatic NSCLC, with no sensitizing EGFR mutation or ALK translocation, who have progressed following treatment with platinum-containing chemotherapy and anti-PD-L1/PD-1 antibody, administered concurrently or sequentially.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04471428 GO41892
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

All	#18 Years	No

How does the CONTACT-01 clinical trial work? This clinical trial is recruiting people who have a type of disease called non-small cell lung cancer, or NSCLC. In order to take part, patients must have NSCLC that has spread to other parts of the body (known as ‘metastatic’).

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus cabozantinib versus docetaxel alone on patients with metastatic NSCLC. In this clinical trial, you will get either atezolizumab plus cabozantinib or docetaxel alone.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have previously received treatment for metastatic NSCLC with an anti-PD-L1/PD-1 antibody and platinum-containing chemotherapy.

You must not have previously received cabozantinib or docetaxel, or certain combinations of treatments. If your NSCLC shows certain genetic changes (called mutations), you may not be able to take part. You must not have any other significant health issues.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?
Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given either:

- Atezolizumab, given through a drip as an infusion into the vein every 3 weeks, plus cabozantinib, given as a tablet to take every day

- OR docetaxel alone, given through a drip as an infusion into the vein every 3 weeks

You will have an equal chance of being placed in either group.

Although neither you nor your clinical trial doctor can choose which group you are in, you and your doctor will know which treatment(s) you are receiving.

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment atezolizumab plus cabozantinib or docetaxel alone for as long as it can help you. You are free to stop this treatment at any time. You will be seen regularly by the clinical trial doctor every 3 weeks. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After being given your last dose, you will be contacted by the clinical trial staff approximately every 3 months, either in person or over the phone.

What happens if I am unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04471428

Inclusion Criteria:

- Histologically or cytologically confirmed metastatic NSCLC
- Documented radiographic disease progression during or following treatment with platinum-containing chemotherapy and anti-PD-L1/PD-1 antibody, administered concurrently or sequentially for metastatic NSCLC
- Measurable disease per RECIST v1.1 outside CNS as assessed by investigator
- Known PD-L1 status or availability of tumor tissue for central PD-L1 testing
- ECOG Performance Status score of 0 or 1
- Recovery to baseline or Grade <=1 NCI CTCAE v5.0 from toxicities related to any prior treatments, unless adverse events are clinically nonsignificant and/or stable on supportive therapy in the opinion of the investigator
- 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 contraception, and agreement to refrain from donating eggs,
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating sperm.

Exclusion Criteria:

- Prior therapy with the following agents for NSCLC: Cabozantinib, Docetaxel, Combination of an anti-PD-L1/PD-1 antibody concurrently with a vascular endothelial growth factor (VEGF)R targeting tyrosine kinase inhibitor (TKI)
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Documentation of known sensitizing mutation in the EGFR gene or ALK fusion oncogene
- Patients with known ROS1 rearrangements, BRAF V600E mutations, or other actionable oncogenes with approved therapies if available
- 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 (more frequently than once monthly)
- Severe hepatic impairment
- Uncontrolled or symptomatic hypercalcemia
- Any other active malignancy at the time of initiation of study treatment or diagnosis of another malignancy within 3 years prior to initiation of study treatment that requires active treatment, except for locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, incidental prostate cancer, or carcinoma in situ of the prostate, cervix, or breast
- Stroke, transient ischemic attack, myocardial infarction or other symptomatic ischemic events within 6 months of initiation of study treatment
- Significant vascular disease within 6 months of initiation of study treatment
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- Active tuberculosis
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia, or any active infection that, in the opinion on the investigator, could impact patient safety
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment
- Current treatment with anti-viral therapy for HBV
- 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 study
- Pregnant or lactating females, or intention of becoming pregnant during the treatment with atezolizumab in combination with cabozantinib in the experimental arm or during the treatment with docetaxel in the control arm, or within 5 months after the final dose of atezolizumab and/or 4 months after the final dose of cabozantinib, whichever is later.
- Ongoing Grade >= 2 sensory or motor neuropathy
- Active or history of autoimmune disease or immune deficiency, including, but not limited to, myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, antiphospholipid antibody syndrome, granulomatosis with polyangiitis, Sjögren syndrome, Guillain-Barré syndrome, or multiple sclerosis with the following exceptions: Patients with a history of autoimmune-mediated hypothyroidism who are on thyroid replacement hormone are eligible for the study. Patients with controlled Type 1 diabetes mellitus are eligible for the study. Patients with eczema, psoriasis, lichen simplex chronicus, or vitiligo with dermatologic manifestations only are eligible for the study provided all of following conditions are met: Rash must cover < 10% of body surface area.
- Pharmacologically uncompensated, symptomatic hypothyroidism
- 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
- Prior allogeneic stem cell or solid organ transplantation

- Administration of 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
- Treatment with systemic immunostimulatory agents (including, but not limited to, interferon and interleukin 2) within 4 weeks or 5 drug-elimination half-lives (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, with the following exceptions: Patients who received acute, low-dose systemic immunosuppressant medication or a one-time pulse dose of systemic immunosuppressant medication are eligible for the study after Medical Monitor confirmation has been obtained. Patients who received mineralocorticoids, inhaled or low-dose systemic corticosteroids for COPD or asthma, or low-dose corticosteroids for orthostatic hypotension or adrenal insufficiency are eligible for the study.
- 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 formulation
- Known allergy or hypersensitivity to any component of the cabozantinib formulation
- History of severe hypersensitivity to docetaxel or to other drugs formulated with polysorbate 80
- Concomitant anticoagulation with coumarin agents, direct thrombin inhibitor dabigatran, direct factor Xa inhibitor betrixaban, or platelet inhibitors
- History of risk factors for torsades de pointes
- Corrected QT interval corrected through use of Fridericia's formula (QTcF) > 480 ms per ECG within 14 days before initiation of study treatment
- Uncontrolled hypertension defined as systolic blood pressure > 150 mm Hg or diastolic BP > 90 mm Hg despite optimal antihypertensive treatment
- Tumors invading the GI-tract, active peptic ulcer disease, acute pancreatitis, acute obstruction of the pancreatic or biliary duct, appendicitis, cholangitis, cholecystitis, diverticulitis, gastric outlet obstruction, or inflammatory bowel disease
- Abdominal fistula, bowel obstruction, GI perforation, or intra-abdominal abscess within 6 months before initiation of study treatment
- Known cavitating pulmonary lesion(s) or known endobronchial disease manifestation
- Lesions invading major pulmonary blood vessels
- Clinically significant hematuria, hematemesis, hemoptysis of > 0.5 teaspoon (2.5 mL) of red blood, coagulopathy, or other history of significant bleeding within 3 months before initiation of study treatment
- Serious non-healing wound/ulcer/bone fracture
- Malabsorption syndrome
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption are also excluded.
- Requirement for hemodialysis or peritoneal dialysis
- Inability to swallow tablets