ForPatients
by Roche

CarcinomaNon-Small Cell Lung Cancer (NSCLC)

A clinical trial to test platinum-doublet chemotherapy with or without atezolizumab in people with non-small cell lung cancer (NSCLC) who have had surgery

A Study Evaluating the Efficacy and Safety of Adjuvant Platinum-Doublet Chemotherapy, With or Without Atezolizumab, in Patients Who Are ctDNA Positive After Complete Surgical Resection of Stage IB to Select IIIB Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Withdrawn		NCT04611776 YO41867

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, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Adjuvant Platinum-Doublet Chemotherapy, With or Without Atezolizumab, in Patients Who Are ctDNA Positive After Complete Surgical Resection of Stage IB to Select IIIB Non-Small Cell Lung Cancer

Trial Summary:

This is a Phase II, multicenter, double-blind, randomized study designed to evaluate the efficacy and safety of adjuvant treatment with atezolizumab in combination with platinum-doublet chemotherapy followed by atezolizumab compared with adjuvant placebo in combination with platinum-doublet chemotherapy followed by placebo in patients with Stage IB to IIIB (T3N2) NSCLC following surgical resection who are positive for ctDNA.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT04611776 YO41867
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the CATHAYA clinical trial work?

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This clinical trial is recruiting people who have a type of disease called non-small cell lung cancer (NSCLC). In order to take part, patients must have NSCLC that has been resected (surgically removed). Patients will also be tested to see if they have circulating tumour DNA (ctDNA; fragments of genetic material that have been released from a dying cancer cell) in their blood.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus adjuvant (after surgery) platinum-doublet chemotherapy against placebo plus adjuvant platinum-doublet chemotherapy in patients who have had their NSCLC completely removed with surgery, and have a positive ctDNA result (ctDNA+).

If you take part in this clinical trial, you will receive either atezolizumab plus adjuvant platinum-doublet chemotherapy or placebo plus adjuvant platinum-doublet chemotherapy.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with NSCLC that has been removed with surgery.

You must not have had any previous treatment for NSCLC, or have NSCLC with mutations in the ALK or EGFR genes (a sample of your tumour will be tested for this). If you have other medical conditions, you may not be able to take part in this clinical trial.

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?

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Patients who have a positive ctDNA result (ctDNA+) will be split into two groups randomly (like flipping a coin) and given either:

- Atezolizumab plus adjuvant platinum-doublet chemotherapy as infusions into the vein every three weeks (for four doses), followed by atezolizumab every four weeks (for ten doses)
- OR placebo plus adjuvant platinum-doublet chemotherapy as infusions into the vein every three weeks (for four doses), followed by placebo every four weeks (for ten doses)

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

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’) in the place of atezolizumab. A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in if your safety is at risk.

If you have a negative ctDNA result (ctDNA–), you will either be observed with no treatment or given platinum-doublet chemotherapy, based on your doctor’s decision and your disease stage. This will help the clinical trial team to understand how well standard treatments work for treating patients who have had their NSCLC surgically removed.

How often will I be seen in follow-up appointments and for how long?

If you are ctDNA+, you will be given the clinical trial treatment atezolizumab plus adjuvant platinum-doublet chemotherapy OR placebo plus adjuvant platinum-doublet chemotherapy for roughly 12 weeks, followed by atezolizumab OR placebo for roughly ten months. You are free to stop this treatment at any time.

After being given treatment, you will still be seen regularly by the clinical trial doctor. While you are receiving treatment, these visits will be roughly every three to four weeks. After this, the visits will be between every three and six months and will include blood tests and CT scans to check if your disease has returned. If your NSCLC comes back, your visits will stop.

If you are ctDNA–, your doctor will decide on your treatment plan and this will determine how often you need to visit the clinic.

Your total time in the study will depend on how your cancer responds to treatment.

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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 https://clinicaltrials.gov/ct2/show/record/NCT04611776

Trial-identifier: NCT04611776

Inclusion Criteria:

- Complete resection (R0) and pathologically confirmed Stage IB to select IIIB NSCLC (8th edition)
- Submission of pre-surgery blood sample and surgically resected tumor tissue slides or block
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Normal life expectancy excluding lung cancer mortality risk
- Positive ctDNA status in plasma confirmed by central laboratory testing after surgical resection and prior to start of adjuvant therapy.

Exclusion Criteria:

- Resected NSCLC with positive margins (R1 or R2)
- NSCLC with histology of large cell neuroendocrine carcinoma or sarcomatoid carcinoma
- Mixed NSCLC and SCLC histology
- Any prior therapy for lung cancer, including neoadjuvant therapy, or radiotherapy
- NSCLC with an activating EGFR mutation or ALK fusion oncogene
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies

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