ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A study evaluating the efficacy and safety of neoadjuvant treatment with atezolizumab or placebo in combination with platinum-based chemotherapy in patients with resectable stage II, IIIA, or select IIIB non-small cell lung cancer

A Study of Neoadjuvant Atezolizumab Plus Chemotherapy Versus Placebo Plus Chemotherapy in Patients With Resectable Stage II, IIIA, or Select IIIB Non-Small Cell Lung Cancer (IMpower030)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT03456063 2023-504209-35-00 GO40241

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, Double-Blinded, Multicenter, Randomized Study Evaluating the Efficacy and Safety of Neoadjuvant Treatment With Atezolizumab or Placebo in Combination With Platinum-Based Chemotherapy in Patients With Resectable Stage II, IIIA, or Select IIIB Non-Small Cell Lung Cancer

Trial Summary:

This is a randomized, double-blinded study designed to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of neoadjuvant treatment with atezolizumab (MPDL3280A) or placebo in combination with platinum-based chemotherapy in participants with resectable Stage II, IIIA, or select IIIB non-small cell lung cancer (NSCLC) followed by open-label adjuvant/postoperative atezolizumab or best supportive care and monitoring.

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

NCT03456063 2023-504209-35-00 GO40241
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

All	# 18 Years	No

How does the IMpower030 clinical trial work? This clinical trial is recruiting people who have a specific type of lung cancer called ‘non-small cell lung cancer’ or NSCLC. This includes two types of lung cancer, which your doctor may refer to as adenocarcinoma and squamous cell carcinoma.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must not have had any prior history of lung cancer or any previous treatment for your current cancer, other than pain medication.

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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

You will have some further tests, which may include taking a tumour sample (or this may have already been taken from the first operation), blood tests and physical examinations, to make sure that you will be able to safely take the treatments given in this clinical trial. Some of these tests and procedures may be part of your regular medical care and 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 and what other treatments are available so that you may decide if you still want to take part.

If you agree to take part in this clinical trial, and your doctor confirms the stage of your cancer and that it can be removed with surgery, then you may be able to be given treatment for your lung cancer.

What treatment will I be given if I join this clinical trial? Everyone who joins the clinical trial will be split into two groups randomly (like flipping a coin) and given one of two different treatments.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given an injection into your vein containing no active drug (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

- Either you will be given the new drug, atezolizumab, and chemotherapy into your vein (this is called an 'intravenous infusion') once every 3 weeks for 4 treatment cycles.
- Or you will be given chemotherapy into your vein and the placebo treatment instead of atezolizumab once every 3 weeks for 4 treatment cycles.

How often will I be seen in follow-up appointments, and for how long? Whichever treatment you are given, you will have surgery to remove your cancer.

After surgery, if you have been given atezolizumab, you will be given 16 rounds of treatment with atezolizumab once every 3 weeks (without the chemotherapy).

If you were not given atezolizumab before surgery (meaning you were given placebo treatment) you will be given other care that will help relieve the symptoms caused by your treatment, surgery or cancer and your doctor(s) will meet with you every 6 weeks after your surgery for a year to assess your well-being and recovery.

A year after your surgery, you will need to meet with your doctor periodically for about 6.5 years to ensure your disease has not returned.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Histologically or cytologically confirmed, resectable Stage II, IIIA, or Select IIIB (T3N2 only) NSCLC of squamous or non-squamous histology. Staging should be based on the 8th edition of the AJCC/UICC staging system
- Evaluation by an attending thoracic surgeon to confirm eligibility for an R0 resection with curative intent
- Adequate pulmonary and cardiac function to undergo surgical resection
- Measurable disease as defined by RECIST v1.1
- Adequate hematologic and end organ function
- Negative HIV test at screening
- Negative for active HBV and HCV at screening
- Adequate tissue for PD-L1 IHC assessment

Exclusion Criteria:

- NSCLC with histology of large cell neuroendocrine carcinoma or sarcomatoid carcinoma
- Mixed NSCLC and small cell lung cancer histology
- Any prior therapy for lung cancer
- Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death treated expected curative outcome
- Non-squamous NSCLC histology with activating ALK and EGFR mutation
- Pregnant or lactating women
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or evidence of active of active pneumonitis on screening chest Computed Tomography (CT) scan
- Prior treatment with cluster of differentiation 137 (CD137) agonist or immune checkpoint blockade therapies, anti-programmed-death-1 (anti-PD-1), and anti-PD-L1 therapeutic antibody
- Severe infection within 4 weeks prior to randomization

- Significant history of cardiovascular disease