ForPatients

by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Clinical Trial to Compare Atezolizumab plus Chemotherapy versus Chemotherapy Alone Before Surgery in Patients with Non-Small Cell Lung Cancer (IMpower030)

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 GO40241

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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 GO40241 Trial Identifiers				
Eligibility Criteria:				
Gender All	Age >= 18 Years		Healthy Volunteers	

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.

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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, 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).

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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.

What happens if I'm unable to take part in this clinical trial? If the stage of your lung cancer does not match what this trial is looking at, you will not be able to take part in this trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/record/NCT03456063

Trial-identifier: NCT03456063