ForPatients
by Roche

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

A clinical trial to compare atezolizumab given as an injection under the skin, with atezolizumab given as an infusion into the vein, in people with lung cancer who have previously received treatment with chemotherapy

A Study to Investigate Atezolizumab Subcutaneous in Patients With Previously Treated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	23 Countries	NCT03735121 2018-002328-18 BP40657

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 Randomized, Multicenter, Phase Ib/III Study to Investigate the Pharmacokinetics, Efficacy, and Safety of Atezolizumab Subcutaneous Compared With Atezolizumab Intravenous in Patients With Previously Treated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Summary:

This study will evaluate the pharmacokinetics, safety, and efficacy of atezolizumab subcutaneous (SC) compared with atezolizumab IV in participants with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have not been exposed to cancer immunotherapy (CIT) and for whom prior platinum-based therapy has failed. The study is comprised of two parts, as follows: A dose-finding part (Part 1, Phase Ib) will aim to identify the dose of atezolizumab SC to be tested in Part 2. A dose-confirmation part (Part 2, Phase III, randomized) will aim to confirm that the dose moved forward from Part 1 yields drug exposure that is comparable to that of atezolizumab IV.

Hoffmann-La Roche
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Phase 3
Phase

NCT03735121 2018-002328-18 BP40657
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the BP40657 clinical trial work? 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 ‘locally advanced’ (in the lung and lymph nodes) or ‘metastatic’ (has spread to other parts of the body) NSCLC that has previously been treated with chemotherapy.

The purpose of this clinical trial is to compare the effects, good or bad, of two different ways of giving atezolizumab in patients with locally advanced or metastatic NSCLC. If you take part in this clinical trial, you will receive atezolizumab either as an infusion into the vein or as an injection under the skin.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with locally advanced or metastatic NSCLC that either did not get better with chemotherapy, or came back (recurred) within 6 months of chemotherapy treatment.

You must not have any uncontrolled brain or spinal cord tumours. If you have previously received particular treatments within a certain amount of time, you may not be able to take part. If you are pregnant or breastfeeding you will not be able to take part.

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 very 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 can become pregnant) will need to either not have heterosexual intercourse or use contraception for safety reasons.

What treatment will I be given if I join this clinical trial? This study is being done in two parts. Part 1 is looking at different doses of atezolizumab to find the dose of atezolizumab

given as an injection under the skin to be tested in Part 2. In Part 2, the dose found in Part 1 will be used to compare the effects of atezolizumab given as an injection under the skin, with atezolizumab given as an infusion into the vein.

Everyone who joins Part 2 of the clinical trial will be allocated into two groups by chance.

- Group A will receive atezolizumab, given as an infusion into the vein
- Group B will receive atezolizumab, given as an injection under the skin

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment atezolizumab as an infusion into the vein or as an injection under the skin, for as long as it can help you. Your treatment visits will also include checks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After being given your last dose of treatment, you will occasionally be contacted by the clinical trial doctor via telephone or asked to return for clinic visits.

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/NCT03735121

Trial-identifier: NCT03735121

Inclusion Criteria:

- Histologically or cytologically documented locally advanced or metastatic NSCLC
- Prior platinum-containing regimen or disease recurrence # 6 months since prior platinum-based adjuvant/neoadjuvant regimen.
- Measurable disease as defined by RECIST v1.1
- ECOG Performance Status of 0 or 1
- Life expectancy #12 weeks
- Adequate hematologic and end-organ function

Additional Inclusion Criteria (Part 2 Only) • Availability of tissue and known EGFR status

Exclusion Criteria:

- Symptomatic, untreated, or actively progressing CNS metastases
- Uncontrolled or symptomatic hypercalcemia

- Pregnancy or breastfeeding
- 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
- Severe infection # 4 weeks
- Treatment with therapeutic oral or IV antibiotics # 2 weeks prior to study treatment
- Significant cardiovascular disease
- Prior allogeneic stem cell or solid organ transplantation
- Treatment with a live, attenuated vaccine # 4 weeks
- Treatment with systemic immunostimulatory agents # 4 weeks or 5 half-lives of the drug
- Treatment with systemic immunosuppressive medication # 2 weeks

Additional Exclusion Criteria (Part 2 Only)

• Tested tumor PD-L1 expression status with an intention to treat the patient if positive