ForPatients
*by Roche*

Non-Small Cell Lung Cancer (NSCLC)

# A clinical trial to compare tiragolumab plus atezolizumab and chemotherapy with pembrolizumab and chemotherapy in people with untreated advanced non-small cell lung cancer

A Study of Tiragolumab in Combination With Atezolizumab Plus Pemetrexed and Carboplatin/Cisplatin Versus Pembrolizumab Plus Pemetrexed and Carboplatin/Cisplatin in Participants With Previously Untreated Advanced Non-Squamous Non-Small Cell Lung Cancer

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 23 Countries | NCT04619797 2020-002851-39 BO42592 |

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

## *Trial Summary:*

The purpose of this study is to evaluate the efficacy, safety, and pharmacokinetics of tiragolumab in combination with atezolizumab plus pemetrexed and carboplatin/cisplatin (Arm A) compared with placebo in combination with pembrolizumab plus pemetrexed and carboplatin/cisplatin (Arm B) in participants with previously untreated, locally advanced unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC). Eligible participants will be randomized in a 1:1 ratio to receive one of the following treatment regimens during the induction phase: - Arm A: Tiragolumab plus atezolizumab plus pemetrexed and carboplatin or cisplatin - Arm B: Placebo plus pembrolizumab plus pemetrexed and carboplatin or cisplatin Following the induction phase, participants will continue maintenance therapy with either tiragolumab in combination with atezolizumab and pemetrexed (Arm A) or placebo in combination with pembrolizumab and pemetrexed (Arm B).

**Hoffmann-La Roche**
Sponsor

**Phase 2/Phase 3**
Phase

**NCT04619797 2020-002851-39 BO42592**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|

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| All | >=18 Years | No |
|---|---|---|

**How does the BO42592 clinical trial work?** This clinical trial is recruiting people who have a particular type of lung cancer called non-small cell lung cancer ( **NSCLC**). In order to take part, patients must have NSCLC that is locally advanced (in the lung and lymph nodes in the middle of the chest), inoperable (cannot be removed by surgery), and for which they have not received any previous treatment.

The purpose of this clinical trial is to compare the effects, good or bad, of tiragolumab plus atezolizumab plus chemotherapy versus placebo plus pembrolizumab and chemotherapy in patients with NSCLC. In this clinical trial, you will get either tiragolumab plus atezolizumab plus chemotherapy or placebo plus pembrolizumab and chemotherapy.

**How do I take part in this clinical trial?**
To be able to take part in this clinical trial, you must be diagnosed with locally advanced, inoperable or metastatic NSCLC.

You must not have received any previous treatment for advanced NSCLC or have tumours with a mutation in the epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) gene. If you have received treatment for an earlier diagnosis of NSCLC, this must have been at least 12 months prior.

If you think this clinical trial may be suitable for you and you 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 two different groups randomly (like flipping a coin). Both groups will

first enter the ‘Induction Phase’ and then after 3 months they will enter the ‘Maintenance Phase’

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

**Induction Phase** During this part of the trial, patients in each group will be given the following treatments every 3 weeks for 4 rounds of treatment:

- Group A: atezolizumab, given as an infusion into the vein, followed by tiragolumab given as an infusion into the vein, followed by chemotherapy (pemetrexed followed by either carboplatin or cisplatin, both given as an infusion into the vein)
- Group B: pembrolizumab, given as an infusion into the vein, followed by placebo, given as an infusion into the vein, followed by chemotherapy (pemetrexed followed by either carboplatin or cisplatin, both given as an infusion into the vein)

**Maintenance Phase** After completing the Induction Phase, patients will enter the Maintenance Phase. During this part of the trial, patients in each group will no longer receive carboplatin or cisplatin as part of their chemotherapy. However, all other treatments will remain the same:

- Group A: atezolizumab, given as an infusion into the vein, followed by tiragolumab given as an infusion into the vein, followed by chemotherapy (pemetrexed, given as an infusion into the vein)
- Group B: pembrolizumab, given as an infusion into the vein, followed by placebo, given as an infusion into the vein, followed by chemotherapy (pemetrexed, given as an infusion into the vein)

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a medicine with no active ingredients (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.

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

**How often will I be seen in follow-up appointments and for how long?** You will be given the clinical trial treatment, atezolizumab plus tiragolumab and chemotherapy OR pembrolizumab plus placebo and chemotherapy, approximately every 3 weeks. The status of your cancer will be checked every 6 weeks for approximately 11 months, and then every 9 weeks. You will continue to receive clinical trial treatment until your cancer worsens or your doctor determines there is no benefit of continuing treatment. You are free to stop this treatment at any time.

After your final dose, your doctor will follow-up with you about every 3 months at the hospital or by telephone for as long as you agree to it.

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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

Trial-identifier: NCT04619797