ForPatients
by Roche

A clinical trial to look at how well tiragolumab plus atezolizumab and chemotherapy worked to treat triple-negative breast cancer (TNBC) that was in its early stages or had already spread to other parts of the body

A Study of the Safety, Efficacy, and Pharmacokinetics of Tiragolumab in Combination With Atezolizumab and Chemotherapy in Participants With Triple-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	0 Countries	NCT04584112 2020-000531-47 CO42177

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 safety, efficacy, and pharmacokinetics of tiragolumab in combination with atezolizumab and chemotherapy in participants with metastatic and early triple-negative breast cancer (TNBC).

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT04584112 2020-000531-47 CO42177
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the CO42177 clinical trial work?

This clinical trial is recruiting people who have a type of disease called triple-negative breast cancer (TNBC). TNBC is breast cancer that does not have HER2, oestrogen or progesterone receptors on the surface of its cells. This clinical trial will recruit patients into two different cohorts (Cohort A and Cohort B), depending on how far their TNBC has spread.

The purpose of this clinical trial is to test the safety of tiragolumab in combination with atezolizumab and chemotherapy, and to understand the way your body processes the combination. The clinical trial will also look at how effective the combination is at fighting TNBC.

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 TNBC:

- To take part in Cohort A, you must have TNBC that has spread to other parts of your body (metastatic TNBC), which cannot be removed with surgery. You must not have already had treatment for your metastatic TNBC. Researchers must also be able to detect a protein called PD-L1 on the surface of your TNBC cells when they look at them under a microscope
- To take part in Cohort B, you must have TNBC that is in its early stages and has not spread beyond the lymph nodes in the armpit. Your treatment plan must include surgery to remove your TNBC after completing your treatment, which may require total or partial removal of the breast (mastectomy)

You must not be pregnant or breastfeeding, or intend to become pregnant while on the clinical trial or soon after. You may not be able to take part in this clinical trial if you have previously received certain medications or have a history of certain other medical conditions.

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 measures 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 cohorts (Cohort A or B) depending on how far their TNBC has spread.

In Cohort A (metastatic TNBC), patients will be given tiragolumab and atezolizumab as infusions into the vein on Day 1 of every 28-day cycle, as well as nab-paclitaxel as an infusion into the vein on Days 1, 8 and 15 of every 28-day cycle.

In Cohort B (early TNBC), patients will be split into two groups randomly (like flipping a coin) and given either

- Tiragolumab and atezolizumab as infusions into the vein every two weeks, as well as nab-paclitaxel as an infusion into the vein every week for a total of 12 weeks, and carboplatin as an infusion into the vein every three weeks for four doses, followed by tiragolumab and atezolizumab with doxorubicin and cyclophosphamide as infusions into the vein every two weeks for four doses
- OR tiragolumab and atezolizumab as infusions into the vein every two weeks, as well as nab-paclitaxel as an infusion into the vein every week for a total of 12 weeks, followed by tiragolumab and atezolizumab with doxorubicin and cyclophosphamide as infusions into the vein every two weeks for four doses

In Cohort B, you will have an equal chance of being placed in either group. Patients treated in Cohort B will also be given G-CSF or GM-CSF as a supportive treatment alongside their chemotherapy, to reduce the risk of side effects.

This is an open-label clinical trial. This means that both you and your clinical trial doctor will know which treatment you are receiving.

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

How long you are given the clinical trial treatment for will depend on whether you are treated in Cohort A or B.

- In Cohort A, you will be given the clinical trial treatment until your breast cancer worsens or you have medically unacceptable side effects
- In Cohort B, you will be given the clinical trial treatment for roughly 19 weeks, before you undergo surgery to remove your TNBC

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 roughly every three months. These appointments may be hospital visits or phone calls and will include checks to see how you have responded to treatment and whether you have started any new treatments since.

What happens if I am unable to take part in this clinical trial?

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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: NCT04584112