ForPatients

by Roche

Triple Negative Breast Cancer Breast Cancer

A clinical trial to look at how safe and effective atezolizumab plus nabpaclitaxel is for treatment of triple-negative breast cancer (TNBC) that cannot be removed with surgery

A Study of Atezolizumab (Tecentriq) Plus Nab-Paclitaxel or Paclitaxel in the Treatment of Unresectable Locally Advanced or Metastatic Triple#Negative Breast Cancer

Trial Status Trial Runs In Trial Identifier

Active, not recruiting 13 Countries NCT04148911 2019-002488-91

MO39874

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

Trial Summary:

Study MO39874 is an open-label, Phase IIIb, single arm, global study conducted in participants with unresectable locally advanced or metastatic PD-L1-positive Triple-Negative Breast Cancer (TNBC) who have not received chemotherapy for their unresectable locally advanced or metastatic disease.

| Hoffmann-La Roche Sponsor | | Phase 3 Phase | |
|--|-------------------|-----------------------|--|
| NCT04148911 2019-002488-91 MO39874 Trial Identifiers | | | |
| Eligibility Criter | ria: | | |
| Gender All | Age >=18 Years | Healthy Volunteers No | |

How does the MO39874 clinical trial work?

This clinical trial is recruiting people who have a particular type of breast cancer called 'triple-negative breast cancer' or TNBC. In order to take part, patients must have inoperable TNBC that has spread to other parts of the body.

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The purpose of this clinical trial is to look at the effects, good or bad, of atezolizumab plus nab-paclitaxel in patients with TNBC. In this clinical trial, you will be treated with atezolizumab plus nab-paclitaxel.

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 inoperable TNBC that has spread to other parts of your body. Doctors must also be able to detect a protein called PD-L1 on the surface of the immune cells that infiltrate your tumour, when looking through a microscope.

You must not have previously received treatment for your inoperable TNBC (radiotherapy is allowed) and you must not be pregnant or breastfeeding. If you have certain other medical conditions or have previously received certain other treatments, you may also not be able to take part in this clinical trial.

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 medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be given:

 Atezolizumab as an infusion into your vein on Day 1 and Day 15 of every 28-day (4week) cycle

AND

 Nab-paclitaxel as an infusion into your vein on Day 1, Day 8 and Day 15 of every 28day (4-week) cycle

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

You will be given the clinical trial treatment atezolizumab plus nab-paclitaxel for as long as it can help you. You are free to stop this treatment at any time. During the clinical trial you will have regular visits with your clinical trial doctor so that he/she can see how you are responding to treatment.

After being given treatment, you will still be contacted regularly every three months (either by phone or with a clinic visit) for as long as you agree.

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/NCT04148911

Trial-identifier: NCT04148911