ForPatients
by Roche

Triple Negative Breast Cancer Breast Cancer

A clinical trial to compare ipatasertib plus atezolizumab and paclitaxel versus a placebo plus different combinations of ipatasertib, atezolizumab and paclitaxel in people with triple-negative breast cancer.

A Study of Ipatasertib in Combination With Atezolizumab and Paclitaxel as a Treatment for Participants With Locally Advanced or Metastatic Triple-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	37 Countries	NCT04177108 2019-000810-12 CO41101

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 study evaluated the efficacy and safety of ipatasertib in combination with atezolizumab and paclitaxel in locally advanced or metastatic Triple-Negative Breast Cancer (TNBC) previously untreated in this setting.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04177108 2019-000810-12 CO41101
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the IPATunity170 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, you must have advanced breast cancer that cannot be fully removed with surgery or that has spread to other parts of your body (known as metastatic breast cancer).

The purpose of this clinical trial is to compare the effects, good or bad, of ipatasertib plus atezolizumab and paclitaxel versus placebo plus different combinations of ipatasertib,

atezolizumab and paclitaxel in patients with advanced or metastatic TNBC. All patients who join this clinical trial will receive either ipatasertib plus atezolizumab and paclitaxel or ipatasertib plus placebo and paclitaxel or placebo plus paclitaxel or placebo plus atezolizumab and paclitaxel.

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 advanced or metastatic TNBC that cannot be fully removed with surgery.

You cannot join the trial if you are pregnant or breastfeeding.

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 split into 2 groups based on whether their cancer tests positive for PD-L1.

Group 1 – for patients with breast cancer that is not PD-L1-positive

Patients in this group will be split into 3 groups randomly and given either:

- ipatasertib (given as tablets to swallow every day for 3 weeks and then no tablets taken for 1 week) plus atezolizumab (given as an infusion into your vein every 2 weeks) and paclitaxel (given as an infusion into your vein every week for 3 weeks and then not given for 1 week)
- OR ipatasertib (given as tablets to swallow every day for 3 weeks and then no tablets taken for 1 week) plus placebo (given as an infusion into your vein every 2 weeks)

and paclitaxel (given as an infusion into your vein every week for 3 weeks and then not given for 1 week)
- OR placebo (given as tablets to swallow every day for 3 weeks and then no tablets taken for 1 week) plus another placebo (given as an infusion into your vein every 2 weeks) and paclitaxel (given as an infusion into your vein every week for 3 weeks and then not given for 1 week)

You will have a 1 in 3 chance of being placed in each group.

OR

Group 2 – for patients with breast cancer that is PD-L1-positive

Patients in this group will be split into 2 groups randomly (like flipping a coin) and given either:

- ipatasertib (given as tablets to swallow every day for 3 weeks and then no tablets taken for 1 week) plus atezolizumab (given as an infusion into your vein every 2 weeks) and paclitaxel (given as an infusion into your vein every week for 3 weeks and then not given for 1 week)
- OR placebo (given as tablets to swallow every day for 3 weeks and then no tablets taken for 1 week) plus atezolizumab (given as an infusion into your vein every 2 weeks) and paclitaxel (given as an infusion into your vein every week for 3 weeks and then not given for 1 week)

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

This is a ‘placebo-controlled’ clinical trial, which means that some patients 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. All patients in Group 1 will be given at least paclitaxel, and all patients in Group 2 will be given at least atezolizumab and paclitaxel.

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 for as long as it can help you. You are free to stop this treatment at any time. While you are being given treatment, you will be monitored to see how you are responding to the treatment and any side effects that you may be having. After being given your last treatment, you will still be seen by the clinical trial doctor within 1 month, and then contacted every 3 months.

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/NCT04177108?term=CO41101&draw=2&rank=1

Trial-identifier: NCT04177108