ForPatients
by Roche

Triple Negative Breast Cancer Breast Cancer

A Clinical Trial of Ipatasertib plus Chemotherapy for Patients with Advanced Triple-Negative Breast Cancer or Hormone Receptor-Positive, HER2-Negative Breast Cancer that has a Change in the PIK3CA/AKT1/PTEN Gene (IPATunity130)

A Study of Ipatasertib in Combination With Paclitaxel as a Treatment for Participants With PIK3CA/AKT1/PTEN-Altered, Locally Advanced or Metastatic, Triple-Negative Breast Cancer or Hormone Receptor-Positive, HER2-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	30 Countries	NCT03337724 2017-001548-36 CO40016

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 will evaluate the efficacy of ipatasertib + paclitaxel versus placebo + paclitaxel in participants with histologically confirmed, locally advanced or metastatic triple-negative breast cancer (TNBC) and in participants with locally advanced or metastatic hormone receptor positive (HR+)/ human epidermal growth factor receptor 2 negative (HER2-) breast adenocarcinoma who are not suitable for endocrine therapy.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03337724 2017-001548-36 CO40016
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the IPATunity130 clinical trial work?

This clinical trial is recruiting people who have a specific type of breast cancer. The aim of this clinical trial is to test whether the new medicine, ipatasertib, is more effective than chemotherapy.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have either ‘triple-negative breast cancer’ or ‘hormone receptor-positive, HER2-negative breast cancer’. Triple-negative breast cancer means that the breast tumour has tested negative for the hormone (progesterone and estrogen) receptors, and for the protein HER2. Hormone receptor-positive, HER2-negative breast cancer means that the breast cancer cells have tested positive for the hormone (progesterone and estrogen) receptors, and negative for the protein HER2.

Your breast cancer must also have a certain type of genetic mutation (a change to the DNA that provides instructions on how our cells should behave) in the genes called ‘PIK3CA/AKT1/PTEN’.

To be able to take part in this clinical trial, you cannot have previously received chemotherapy for advanced breast cancer.

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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of 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 and procedures may be part of your regular medical care and 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. You will also need to have a ‘biopsy’ (a surgical procedure that involves taking a small tissue sample) of your tumour if an appropriate sample of your tumour is not already available.

What treatment will I be given if I join this clinical trial? Everyone who joins the clinical trial will be split into two groups randomly (like flipping a coin) and given one of two different treatments.

This is a ‘placebo-controlled’ clinical trial, which means that while all patients will receive chemotherapy, one-third of patients will receive a placebo instead of ipatasertib. A placebo is a sugar pill with no active drug. The purpose of a placebo-controlled clinical trial (in which neither the doctor nor the patient knows who is receiving placebo) is to understand the benefits of the new drug (in this case ipatasertib).

Every 28 days, you will either be given:

- Chemotherapy into your vein (this is called an ‘intravenous infusion’) once a week for 3 weeks, and a tablet of the new drug ipatasertib each day for 3 weeks.

- Or chemotherapy into your vein once a week for 3 weeks, and the placebo treatment instead of ipatasertib each day for 3 weeks.

You will have a 2 out of 3 chance of being given ipatasertib and chemotherapy, and a 1 out of 3 chance of being given chemotherapy and the placebo treatment instead of ipatasertib.

How often will I be seen in follow-up appointments, and for how long? You will be given the clinical trial treatment (chemotherapy and ipatasertib or placebo) as long as it controls your cancer (until your cancer worsens) and as long as your side effects are manageable. You are free to stop this treatment at any time.

Initially, you will need to go to the clinical trial site at least once a week for treatment to be given. The clinical trial doctor will also check how your cancer is responding to the treatment and discuss any side effects that you may be experiencing. When the clinical trial treatment has stopped, you will be contacted by the clinical trial team either in person or by other methods around once every 3 months for the rest of your life; unless the sponsor ends the trial or you choose to withdraw.

What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

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