ForPatients
by Roche

Triple Negative Breast CancerBreast 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 (IPATunity130)

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

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Double-Blind, Placebo-Controlled, Randomized Phase III Study of Ipatasertib in Combination With Paclitaxel as a Treatment for Patients With PIK3CA/AKT1/PTEN-Altered, Locally Advanced or Metastatic, Triple-Negative Breast Cancer or Hormone Receptor-Positive, HER2-Negative Breast Cancer

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

Trial-identifier: NCT03337724

Inclusion Criteria:

- Women or men aged =>18 years with histologically documented triple-negative breast cancer (TNBC) or HR+/HER2- adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to resection with curative intent
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Adequate hematologic and organ function within 14 days prior to treatment initiation

- Histologically documented TNBC or HR+/HER2- adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to resection with curative intent
- Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Eligible for taxane monotherapy, as per local investigator assessment (e.g., absence of rapid clinical progression, life-threatening visceral metastases, or the need for rapid symptom and/or disease control which may require combination chemotherapy)
- HR+/HER2- breast cancer that is not considered appropriate for endocrine-based therapy and meets one of the following: patient has recurrent disease <=5 years of being on adjuvant endocrine therapy or if patient with de novo metastatic disease have progressed within 6 months of being on first line endocrine therapy.
- Consent to submit a formalin-fixed, paraffin-embedded tumor (FFPE) tissue block or freshly cut unstained, serial tumor slides from the most recently collected tumor tissue for central molecular analysis
- Confirmation of biomarker eligibility using an appropriately validated molecular assay at a diagnostic laboratory, Clinically Laboratory Improvement Amendments (CLIA) or equivalently accredited i.e., valid results from either central testing or local testing of tumor tissue or blood demonstrating PIK3CA/AKT1/PTEN-altered status
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods and agreement to refrain from donating sperm

Exclusion Criteria:

- Treatment with approved or investigational cancer therapy within 14 days prior to treatment initiation
- Any previous chemotherapy for inoperable locally advanced or metastatic TNBC or HR+/HER2- adenocarcinoma of the breast (patients receiving neo/adjuvant chemotherapy eligible provided they have at least a 12 month disease-free interval)
- History of or known presence of brain or spinal cord metastases
- Malignancies other than breast cancer within 5 years prior to treatment initiation (except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer)
- Prior treatment with an Akt inhibitor (prior PI3K or mTOR inhibitors are allowed)
- History of malabsorption syndrome or other condition that would interfere with enteral absorption or results in the inability or unwillingness to swallow pills
- Active infection requiring systemic anti-microbial treatment (including antibiotics, anti-fungals, and anti-viral agents)
- Known human immunodeficiency virus (HIV) infection
- Known clinically significant history of liver disease consistent with Child-Pugh Class B or C, including active viral or other hepatitis, current drug or alcohol abuse, or cirrhosis
- Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to initiation of treatment (or anticipated need during study)
- Pregnant or breastfeeding, or intending to become pregnant during the study
- Clinically significant cardiac dysfunction (including NYHA Class II/III/IV heart failure, left ventricular ejection fraction [LVEF] <50%, active ventricular arrhythmia requiring medication, history of myocardial infarction within 6 months of treatment initiation, clinically significant electrocardiogram [ECG] abnormalities).
- Need for chronic corticosteroid therapy of >=10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids or immunosuppressants for a chronic disease
- Unresolved, clinically significant toxicity from prior therapy, except for alopecia and Grade 1 peripheral neuropathy

- Uncontrolled clinical symptoms including pleural effusion, pericardial effusion, or ascites, tumor-related pain, hypercalcemia (or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy)
- History of Type I or Type II diabetes mellitus requiring insulin
- Grade >=2 uncontrolled or untreated hypercholesterolemia or hypertriglyceridemia
- History of or active inflammatory bowel disease or active bowel inflammation
- Clinically significant lung disease (including pneumonitis, interstitial lung disease, idiopathic pulmonary fibrosis, cystic fibrosis, active infection/ history of opportunistic infections)
- Treatment with strong CYP3A inhibitors or strong CYP3A inducers within 2 weeks or 5 drug-elimination half-lives, whichever is longer, prior to initiation of treatment
- Grade >=2 peripheral neuropathy