ForPatients
by Roche

Breast Cancer Breast Cancer Er-Positive

A clinical trial to compare the safety and effectiveness of ipatasertib plus palbociclib and fulvestrant versus a placebo plus palbociclib and fulvestrant in people with breast cancer

A Study of Ipatasertib Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Hormone Receptor Positive and HER2 Negative Locally Advanced Unresectable or Metastatic Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Terminated	8 Countries	NCT04060862 2019-001072-11 CO41012

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 open-label Phase Ib portion of this study will evaluate the safety and pharmacokinetics of ipatasertib in combination with palbociclib and fulvestrant to identify a dose of ipatasertib that can be combined with palbociclib and fulvestrant in the Phase III portion. The randomized Phase III portion of this study will evaluate the efficacy, safety, and patient-reported outcome (PRO) objectives of ipatasertib + palbociclib + fulvestrant compared with placebo + palbociclib + fulvestrant in patients with HR+ HER2-, locally advanced unresectable or metastatic breast cancer who had relapsed during adjuvant endocrine therapy or progressed during the initial 12 months of first-line endocrine therapy in locally advanced unresectable or metastatic breast cancer.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04060862 2019-001072-11 CO41012
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the CO41012 clinical trial work? This clinical trial is recruiting people who have a particular type of breast cancer. 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). Your cancer must be hormone positive (ER+ and/or PR+) and HER2-negative.

This clinical trial will have 2 parts. The purpose of Part 1 is to see if ipatasertib can be given safely with palbocilib and fulvestrant in patients with advanced or metastatic breast cancer. Part 2 will then compare the effects, good or bad, of ipatasertib plus palbociclib and fulvestrant versus placebo plus palbociclib and fulvestrant in patients with advanced or metastatic breast cancer. All patients who join Part 2 of this clinical trial will receive either ipatasertib plus palbociclib and fulvestrant or placebo plus palbociclib and fulvestrant.

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 hormone positive (ER+ and/or PR+), HER2-negative, advanced or metastatic breast cancer that cannot be fully removed with surgery. If you have not been through the menopause, you will need to be treated with a drug called goserelin or alternative medication, which will reduce the amount of oestrogen your body makes, for at least 28 days before you can receive the trial treatment.

You must not have previously received ipatasertib or fulvestrant and 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? This clinical trial will be split into 2 parts:

Part 1 Part 1 will confirm that the combination of ipatasertib plus palbociclib and fulvestrant is safe and find the best dose of ipatasertib to be used with palbociclib and fulvestrant. Part 1 will include a small number of patients who will be given ipatasertib, palbociclib and fulvestrant as follows:

- First 5–7 days:
    - Ipatasertib given as a tablet to swallow every day
- Rest of Part 1:
    - Ipatasertib and palbociclib (both given as tablets/capsules to swallow every day for 3 weeks and then no tablets/capsules taken for 1 week) and fulvestrant (given as an injection every 2 weeks for the first month and then every 4 weeks after that)

Part 2 If Part 1 confirms that the clinical trial treatment is safe, the trial will move on to Part 2, which will include a much larger number of patients. Everyone who joins Part 2 will be split into 2 groups randomly (like flipping a coin) and given either:

- Ipatasertib (based on the recommended dose found in Part 1) and palbociclib (both given as tablets/capsules to swallow every day for 3 weeks and then no tablets/capsules taken for 1 week) and fulvestrant (given as an injection every 2 weeks for the first month and then every 4 weeks after that)
- OR placebo and palbociclib (both given as tablets/capsules to swallow every day for 3 weeks and then no tablets/capsules taken for 1 week) and fulvestrant (given as an injection every 2 weeks for the first month and then every 4 weeks after that)

In Part 2, you will have an equal chance of being placed in either group.

This part of the trial is ‘placebo-controlled’, which means that one of the groups in Part 2 will be given one medicine with no active ingredients. A placebo is an important scientific control used to show that any differences between the groups are due to the additional treatment being tested and makes sure the doctor or the patients do not sway the results of the clinical trial.

Part 2 of the clinical trial is also ‘double blind’, which means that 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 ipatasertib plus palbociclib and fulvestrant OR placebo plus palbociclib and fulvestrant for as long as it can help you. You are free to stop this treatment at any time. If you join Part 1, after your last treatment, you will be seen by the clinical trial doctor within 1 month. If you join Part 2, after your last treatment, you will still be contacted regularly by the clinical trial doctor every 2–3 months. These checks

will see how you are responding to the treatment and any side effects that you may be having.

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/NCT04060862

Trial-identifier: NCT04060862