ForPatients
by Roche

Breast Cancer Er-Positive Breast Cancer HER2-Positive Breast Cancer

A clinical trial to compare the effectiveness and safety of adding GDC-0077 or a placebo to palbociclib and fulvestrant in people with breast cancer.

A Study Evaluating the Efficacy and Safety of Inavolisib + Palbociclib + Fulvestrant vs Placebo + Palbociclib + Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	28 Countries	NCT04191499 2019-002455-42 WO41554

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, safety, and pharmacokinetics of inavolisib in combination with palbociclib and fulvestrant compared with placebo plus palbociclib and fulvestrant in participants with PIK3CA-mutant, hormone receptor (HR)-positive, HER2-negative locally advanced or metastatic breast cancer whose disease progressed during treatment or within 12 months of completing adjuvant endocrine therapy and who have not received prior systemic therapy for metastatic disease.

Hoffmann-La Roche
Sponsor

Phase 2/Phase 3
Phase

NCT04191499 2019-002455-42 WO41554
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the INAVO120 clinical trial work?
This clinical trial is recruiting people who have a particular type of breast cancer that is hormone receptor (HR)-positive and HER2-negative. In order to take part, patients must

have advanced breast cancer that cannot be fully removed with surgery or that has spread to other parts of their body (known as metastatic breast cancer).

The purpose of this clinical trial is to compare the effects, good or bad, of adding GDC-0077 or placebo to treatment with palbociclib and fulvestrant in patients with breast cancer that has spread to other parts of the body. If you take part in this clinical trial, you will receive either GDC-0077 or placebo in addition to 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 HR-positive, HER2-negative breast cancer that has spread to other parts of the body and cannot be fully removed with surgery. You must be 18 years of age or older. Women who are not yet post-menopausal must be treated with hormone therapy, starting at least 2 weeks before joining the study. Men are also advised to take this hormone therapy.

You must not have received any treatment for your breast cancer since it has been found to have spread to other parts of the body 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.

Before starting the clinical trial, you will be told about the 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 use non-hormonal contraception for safety reasons.

What treatment will I be given if I join this clinical trial?
Everyone who joins this clinical trial will be split equally into 2 groups randomly (like flipping a coin) and given either:

- GDC-0077 (given as a tablet to swallow every day)

- Palbociclib (given as a capsule/tablet to take every day for 3 weeks then no capsule/ tablet taken for 1 week)
- Fulvestrant (given as an injection every 2 weeks for the first month and then every 4 weeks after that)

OR

- Placebo (given as a tablet to swallow every day)
- Palbociclib (given as a capsule/tablet to take every day for 3 weeks then no capsule/ tablet taken for 1 week)
- Fulvestrant (given as an injection every 2 weeks for the first month and then every 4 weeks after that)

You will have a 1 in 2 chance of being placed in either group.

This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a tablet with no active ingredients but will still be given palbociclib and fulvestrant, which is the current standard treatment for this type of breast cancer. A placebo is used to make sure that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, if your safety is at risk, your clinical trial doctor can find out which group you are in.

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment, GDC-0077 OR placebo plus palbociclib and fulvestrant, for as long as it can help you. While receiving the study treatment, you will be seen by the clinical trial doctor to see how you are responding to the treatment and any side effects that you may be having. You are free to stop the study treatment at any time. After stopping the study treatment, you will still be seen by the clinical trial doctor within 1 month. After that, you will then be contacted by the clinical trial doctor every 3 months by telephone calls and/or for clinic visits.

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/NCT04191499?term=WO41554&draw=2&rank=1

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