ForPatients
*by Roche*

Cáncer de mama ER-positivoCáncer de mama HER-2 negativoCáncer de mama localmente avanzado o metastásicoCáncer de mama

# Estudio de evaluación de la eficacia y seguridad de GDC-9545 combinado con palbociclib en comparación con letrozol combinado con palbociclib en participantes con cáncer de mama localmente avanzado o metastásico con receptores de estrógenos positivos y HER2 negativo.

A Study Evaluating the Efficacy and Safety of Giredestrant Combined With Palbociclib Compared With Letrozole Combined With Palbociclib in Participants With Estrogen Receptor-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer (persevERA Breast Cancer)

| Trial Status | Trial Runs In | Trial Identifier |
| --- | --- | --- |
| Activo, sin reclutar | 31 Countries | NCT04546009 2020-000119-66 2023-506911-16-00 BO41843 |

*La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.*

## *Official Title:*

ESTUDIO MULTICÉNTRICO DE FASE III, ALEATORIZADO, DOBLE CIEGO, CONTROLADO CON PLACEBO QUE EVALÚA LA EFICACIA Y SEGURIDAD DE GDC-9545 COMBINADO CON PALBOCICLIB FRENTE A LETROZOL COMBINADO CON PALBOCICLIB EN PACIENTES CON CÁNCER DE MAMA HER2 NEGATIVO, RECEPTOR DE ESTRÓGENO POSITIVO, LOCALMENTE AVANZADO O METASTÁSICO

## *Trial Summary:*

This Phase III, randomized, double-blind, placebo-controlled, multicenter study will evaluate the efficacy and safety of giredestrant combined with palbociclib compared with letrozole combined with palbociclib in patients with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative locally advanced (recurrent or progressed) or metastatic breast cancer.

**Hoffmann-La Roche**
Sponsor

**Phase 3**
Phase

**NCT04546009 2020-000119-66 2023-506911-16-00 BO41843**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

### 1. How does the persevERA clinical trial work?

This clinical trial is recruiting people who have a particular type of breast cancer called oestrogen receptor (ER)-positive, HER2-negative breast cancer.

In order to take part, the tumour may be present within the breast tissue or underarm area and considered inoperable or unsuitable for definitive surgery or radiotherapy (locally advanced) or may have spread to other parts of the body (metastatic).

The purpose of this clinical trial is to compare the effects, both potential benefits and potential risks, of a research medication called GDC-9545 (or giredestrant) plus a standard therapy called palbociclib versus letrozole plus palbociclib (both standard therapies) in women and men with ER-positive, HER2-negative breast cancer that is locally advanced or metastatic. In addition, in both treatment groups, women who are pre- or peri-menopausal and all men who participate will receive a luteinizing hormone-releasing hormone (LHRH) agonist on Day 1 of every 28-day cycle, which is standard treatment for these people, to stop the production of certain sex hormones (oestrogen and progesterone for women and testosterone for men).

In this clinical trial, people will be given either GDC-9545 plus palbociclib (and an LHRH agonist if indicated) or letrozole plus palbociclib (and an LHRH agonist if indicated).

### 2. How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be diagnosed with ER-positive, HER2-negative, locally advanced or metastatic breast cancer, which cannot be cured with the currently available treatments.

You must not have previously received any anti-cancer therapy for locally advanced or metastatic disease that works throughout the whole body. If you have received additional cancer treatment after the primary treatment for early breast cancer you could be eligible, but if you have received certain other treatments within a particular timeframe, you may not be able to take part. If you are pregnant or breastfeeding, you will not be able to take part.

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 are eligible for the clinical trial and will be able to tolerate 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 the potential risks and potential benefits of taking part in the trial. The clinical trial procedures will be explained, and 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 not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or use non-hormonal contraception which is considered to be highly effective for safety reasons. In addition, men who participate in the clinical trial must agree to use a condom in addition to highly effective contraception to protect the partner from exposure to clinical trial medications which might have harmful effects.

**3. What treatment will I be given if I join this clinical trial?**

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin).

Each group will be given one of the following treatments as part of a 28-day cycle:

# GDC-9545 as a capsule (plus a placebo capsule which looks like letrozole but has no active ingredients), taken by mouth every day (Days 1–28) plus palbociclib as a capsule or tablet, taken by mouth on Days 1–21

OR

# Letrozole as a capsule (plus a placebo capsule which looks like GDC-9545 but has no active ingredients), taken by mouth every day (Days 1–28) plus palbociclib as a capsule or tablet, taken by mouth on Days 1–21

In both treatment groups, women who are pre- or peri-menopausal and men will receive a LHRH agonist on Day 1 of every 28-day cycle.

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

As stated, all patients will receive active therapies, but this is a 'placebo-controlled' clinical trial, which means that each group 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 participants 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, your clinical trial doctor can find out which group you are in, but only if your safety is at risk.

**4. How often will I be seen in follow-up appointments and for how long?**

You will be given the clinical trial treatment GDC-9545 plus palbociclib OR letrozole plus palbociclib (and an LHRH agonist, if required) for as long as it can help you. You are free to stop this treatment at any time, and this decision will not affect your ongoing care. During treatment, you will be seen regularly by the clinical trial doctor at least every 4 weeks. These hospital visits will include scans of your tumour to see how you are responding to the treatment and other regular checks to see if you are experiencing any side effects.

After stopping the clinical trial treatment, you will be seen by a clinical trial doctor after 30 days and may be asked to return for further follow-up visits and/or be contacted by telephone approximately every 6 months.

**5. 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 ForPatients page or follow this link to ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT04546009

Trial-identifier: NCT04546009

## *Inclusion Criteria:*

- For women who are premenopausal or perimenopausal and for men: treatment with approved LHRH agonist therapy for the duration of study treatment
- Locally advanced (recurrent or progressed) or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent
- Documented ER-positive tumor and HER2-negative tumor, assessed locally
- Patients who have bilateral breast cancers which are both ER-positive and HER2-negative can be included in the study because the metastases are suitably targeted by the study treatments. If patients have bilateral tumors which are of different biomarker status, then proof of the ER and HER2 status of the metastases is required for study entry
- No history of systemic anti-cancer therapy for locally advanced (recurrent or progressed) or metastatic disease
- Disease recurrence from early-stage breast cancer after standard adjuvant endocrine therapy meeting the protocol-defined criteria of having received at least 24 months of treatment without disease progression during treatment and a disease-free interval since the completion of treatment that was greater than 12 months
- Measurable disease as defined per RECIST v.1.1 or bone only disease which must have at least one predominantly lytic bone lesion confirmed by CT or MRI which can be followed
- Eastern Cooperative Oncology Group Performance Status 0-1
- Adequate organ function

## *Exclusion Criteria:*

- Disease recurrence during or within 12 months of completing prior neoadjuvant or adjuvant treatment with any CDK4/6 inhibitor
- Prior treatment with a selective estrogen receptor degrader (SERD)
- Treatment with any investigational therapy within 28 days prior to study treatment
- Treatment with strong CYP3A inhibitors or inducers within 14 days or 5 drug elimination half-lives (whichever is longer) prior to randomization
- Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term
- Known active uncontrolled or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease
- Active cardiac disease or history of cardiac dysfunction, as defined in the protocol
- Pregnant or breastfeeding