ForPatients
by Roche

Breast Cancer Er-PositiveBreast CancerEarly Breast CancerBreast Cancer HER-2 Negative

A clinical trial to compare the drug giredestrant plus palbociclib with anastrozole plus palbociclib in post-menopausal women with a specific type of early breast cancer called oestrogen receptor (ER)-positive/ human growth factor 2 (HER2)-negative breast cancer

A Study Evaluating the Efficacy, Safety, and Pharmacokinetics of GDC-9545 Plus Palbociclib Compared With Anastrozole Plus Palbociclib for Postmenopausal Women With Estrogen Receptor-Positive and HER2-Negative Untreated Early Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	11 Countries	NCT04436744 2020-001007-16 WO42133

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 Randomized, Multicenter, Open-Label, Two-Arm, Phase II, Neoadjuvant Study Evaluating the Efficacy, Safety, and Pharmacokinetics of GDC-9545 Plus Palbociclib Compared With Anastrozole Plus Palbociclib for Postmenopausal Women With Estrogen Receptor-Positive and HER2-Negative Untreated Early Breast Cancer

Trial Summary:

This is a randomized, multicenter, open-label, two-arm, Phase II study to evaluate the efficacy, safety, and pharmacokinetics of giredestrant versus anastrozole (in the window-of-opportunity phase) and giredestrant plus palbociclib compared with anastrozole plus palbociclib (in the neoadjuvant phase) in postmenopausal women with untreated, estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative, early breast cancer. The study consists of a screening period of up to 28 days, a window-of-opportunity phase for 14 days, followed by a neoadjuvant treatment phase for 16 weeks (four 28-day cycles), surgery, and an end of study visit (28 days after the final dose of study treatment).

Download: Lay Person Summary Results, Thank you Letter

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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NCT04436744 2020-001007-16 WO42133
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	**#18 Years**	**No**

How does the coopERA clinical trial work?

This clinical trial is recruiting post-menopausal women (no longer menstruating) who have been diagnosed with early oestrogen receptor (ER)-positive/human epidermal growth factor 2 (HER2)-negative breast cancer.

ER-positive means that the cells of this type of breast cancer have receptors (special structures on the outside of the cell) that allow them to use the hormone oestrogen to grow. HER2-negative means that your cancer has low levels of a protein called HER2.

The purpose of this study is to compare the effects, good or bad, of giredestrant versus anastrozole alone (single-agent treatment) followed by giredestrant plus palbociclib versus anastrozole plus palbociclib (combination treatment) in patients with your type of early breast cancer. In this study, you will get either giredestrant or anastrozole alone (single-agent treatment) followed by the same drug in combination with palbociclib.

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 early breast cancer, be at least 18 years old at the time of giving informed consent, be post-menopausal and be willing to have surgery to remove your breast cancer tissue after clinical trial treatment.

You must not have previously received any medicine for your breast cancer. If you have previously received certain other medications or have certain other medical conditions, you may not be able to take part in this clinical trial.

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. All patients will be required to provide three tumour tissue samples: one before treatment begins, one during treatment, and one after treatment.

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.

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) and given either:

- Giredestrant alone (single-agent treatment), as a pill, once a day for two weeks
    - Following this you will receive giredestrant once a day for 28 days AND palbociclib as a pill once a day for 21 days of every 28-day treatment cycle
- OR anastrozole alone (single-agent treatment), as a pill, once a day for two weeks
    - Following this you will receive anastrozole once a day for 28 days AND palbociclib as a pill once a day for 21 days of every 28-day treatment cycle

One cycle of combination treatment will last for 28 days and you will have four cycles (four months) of treatment. You will then undergo surgery to remove your breast cancer tissue.

You will have a 1 in 2 (50%) chance of being placed in either group.

This is an open-label trial which means that you and your clinical trial doctor will know which treatment you are receiving.

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

You will receive clinical trial treatment for approximately 18 weeks and then undergo surgery to remove your breast cancer tissue.

You are free to stop this treatment at any time. During this study, you will have approximately 10–11 visits while you are receiving treatment. Most visits will last approximately one hour. Some visits may last up to three hours. After you have completed your clinical trial treatment and have undergone surgery to remove your breast cancer, you will have one final visit with your clinical trial doctor.

The visits will include checks to 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?

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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

Trial-identifier: NCT04436744

Inclusion Criteria:

- Postmenopausal women age #18 years
- Histologically confirmed operable or inoperable invasive breast carcinoma
- Candidate for neoadjuvant treatment and considered appropriate for endocrine therapy
- Willingness to undergo breast surgery after neoadjuvant treatment and to provide three mandatory tumor samples
- Documented estrogen receptor (ER)-positive tumor in accordance to American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines (Allison et al.2020), assessed locally and defined as #1% of tumor cells stained positive on the basis of the most recent tumor biopsy
- Documented progesterone receptor status (positive or negative) as per local assessment
- Documented human epidermal growth factor receptor-2 (HER2)-negative tumor in accordance to 2018 ASCO/CAP guidelines (Wolff et al. 2018), assessed locally on the most recent tumor biopsy
- Ki67 score #5% analyzed centrally or locally
- Eastern Cooperative Oncology Group Performance Status 0-1
- Adequate organ function

Exclusion Criteria:

- Stage IV (metastatic) breast cancer
- Inflammatory breast cancer (cT4d)
- Bilateral invasive breast cancer
- History of invasive breast cancer, ductal carcinoma in situ or lobular carcinoma in situ and other malignancy within 5 years prior to screening
- Previous systemic or local treatment for the primary breast cancer currently under investigation
- History of any prior treatment with aromatase inhibitors (AIs), tamoxifen, selective estrogen receptor down regulator, or cyclin-dependent kinase 4 and 6 inhibitors
- Major surgery within 4 weeks prior to randomization
- Known clinically significant history of liver disease consistent with Child-Pugh Class B or C, including hepatitis
- Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for entry into this study
- History of allergy to anastrozole, or palbociclib or any of its excipients
- Known issues with swallowing oral medication
- History of documented hemorrhagic diathesis, coagulopathy, or thromboembolism
- Active cardiac disease or history of cardiac dysfunction
- Current treatment with medications that are well known to prolong the QT interval
- Active inflammatory bowel disease or chronic diarrhea, short bowel syndrome, or major upper gastrointestinal surgery including gastric resection

- Treatment with strong CYP3A4 inhibitors or inducers within 14 days or 5 drug elimination half-lives prior to randomization
- Known HIV infection
- Serious infection requiring oral or IV antibiotics, or other clinically significant infection within 14 days prior to screening
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study