ForPatients
by Roche

Cáncer de mama Er-positivoCáncer de mama localmente avanzado o metastásicoCáncer de mamaReceptor estrogénico (RE) positivoCáncer de mama Her-2 negativo

Un estudio que compara el uso de GDC-9545 con la terapia hormonal elegida por el médico en personas con cáncer de mama avanzado o metastásico, cuyo tratamiento previo no haya funcionado.

Un estudio que evalúa la eficacia y la seguridad del giredestrant en comparación con la monoterapia endocrina elegida por el médico en pacientes con cáncer de mama metastásico o localmente avanzado, HER2 negativo con receptor de estrógeno positivo tratados previamente

Trial Status	Trial Runs In	Trial Identifier
Activo, no reclutando	17 Countries	NCT04576455 2020-001984-10 WO42312

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:

A Phase II, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of GDC-9545 Compared With Physician's Choice of Endocrine Monotherapy in Patients With Previously Treated Estrogen Receptor-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer

Trial Summary:

This Phase II, randomized, open-label, multicenter study will evaluate the efficacy and safety of giredestrant compared with physician's choice of endocrine monotherapy in participants with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer who have received one or two prior lines of systemic therapy in the locally advanced or metastatic setting.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT04576455 2020-001984-10 WO42312
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

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How does the WO42312 clinical trial work? This clinical trial is recruiting people who have a particular type of breast cancer. In order to take part, patients must have breast cancer that is advanced or metastatic (spread to other parts of the body) and has tested positive for estrogen receptors (ER-positive) and negative for HER2 (HER2-negative).

The purpose of this clinical trial is to compare the effects, good or bad, of GDC-9545 with a doctor's choice of hormonal therapy in patients with this type of breast cancer. If you take part in this clinical trial, you will receive either GDC-9545 or your doctor's choice of hormonal therapy.

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 ER-positive, HER2-negative locally advanced or metastatic breast cancer. You must have received up to two previous treatments for breast cancer, one of which included hormonal therapy, taken for at least 6 months before the cancer got worse.

Your cancer must not have spread to the central nervous system or spinal cord, and you must not have any other significant health conditions.

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, premenopausal women who could become pregnant will need to either not have heterosexual intercourse or take contraceptive medication to avoid becoming pregnant for safety reasons.

Men whose partners who could become pregnant are also requested to use contraception to avoid pregnancy in their partner for safety reasons.

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:

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- GDC-9545, taken as a pill once-daily
- OR a hormonal therapy, taken as prescribed by your doctor

You will have an equal chance of being placed in the two groups.

Men, and women who are not postmenopausal, will also need to take medication known as LHRH-agonist, starting 28 days before the trial starts and then every 28 days throughout the duration of the trial.

How long will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment for as long as it can help you. During the trial, you will have appointments every 2 months for the first 18 months, and then every 3 months after that. These hospital visits will also include checks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After you finish treatment, you will have another visit one month after your last dose. The clinical trial doctors will also follow up with you at 3 months and then every 6 months after that, as long as you agree to it.

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 may suggest other clinical trials that you may be able to take part in or other treatments that you could 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/NCT04576455?term=WO42312&draw=2&rank=1

Trial-identifier: NCT04576455

Inclusion Criteria:

- Women who are postmenopausal or premenopausal/perimenopausal
- For women who are premenopausal or perimenopausal and for men: willing to undergo and maintain treatment with approved LHRH agonist therapy for the duration of study treatment
- Locally advanced or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent
- Documented ER-positive tumor and HER2-negative tumor, assessed locally
- Disease progression after treatment with one or two lines of systemic therapy (but not more than one prior targeted therapy) in the locally advanced or metastatic setting
- 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 (ECOG) Performance Status 0-1
- Adequate organ function

Exclusion Criteria:

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- Prior treatment with a selective estrogen receptor degrader (SERD), with the exception of fulvestrant, if fulvestrant treatment was terminated at least 28 days prior to randomization
- Treatment with any investigational therapy within 28 days prior to randomization
- Advanced, symptomatic, visceral spread that is at risk of life-threatening complications
- Known active uncontrolled or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease
- Active cardiac disease or history of cardiac dysfunction
- Pregnant or breastfeeding

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