

ForPatients

by Roche

Breast Cancer

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of GDC-0587 as a Monotherapy and in Combination With Giredestrant in Participants With Locally Advanced or Metastatic Estrogen Receptor-Positive and Human Epidermal Growth Factor Receptor 2-Negative (ER+/HER2-) Breast Cancer

Trial Status
Recruiting

Trial Runs In
1 Country

Trial Identifier
NCT07214662 GO46057

The information is taken directly from public registry websites such as [ClinicalTrials.gov](https://clinicaltrials.gov), [EuClinicalTrials.eu](https://euclinicaltrials.eu), [ISRCTN.com](https://isrctn.com), etc., and has not been edited.

Official Title:

A Phase Ia/Ib Dose-Escalation and Expansion Study Evaluating the Safety, Pharmacokinetics, and Activity of GDC-0587 as a Monotherapy and in Combination With Giredestrant in Patients With Locally Advanced Or Metastatic ER-Positive, HER2-Negative Breast Cancer Who Have Previously Progressed During or After CDK4/6 Inhibitor Therapy

Trial Summary:

This is a first-in-human, Phase Ia/Ib, dose-escalation and expansion study evaluating the safety, pharmacokinetics, and activity of GDC-0587 (cyclin-dependent kinase-4 [CDK4] inhibitor) as a monotherapy and in combination with giredestrant in participants with locally advanced or metastatic estrogen receptor-positive and human epidermal growth factor receptor 2-negative (ER+/HER2-) breast cancer who have previously progressed during or after CDK 4/6 inhibitor therapy.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07214662 GO46057
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

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Inclusion Criteria:

- Agreement to adhere to the contraception requirements
- For females of childbearing potential #60 years of age and males: treatment with luteinizing hormone-releasing hormone (LHRH) agonist therapy beginning at least 2 weeks prior to Cycle 1, Day 1 and agreement to continue LHRH agonist therapy for the duration of the study
- Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic
- Previously documented ER+ and HER2- tumor according to American Society of Clinical Oncology (ASCO)/ College of American Pathologists (CAP) or European Society of Medical Oncology (ESMO) guidelines or any national guidelines with criteria conforming to ASCO/CAP or ESMO guidelines
- Disease progression during or following treatment with an approved CDK 4/6 inhibitor, with or without endocrine therapy, in the locally advanced or metastatic setting
- Measurable, or non-measurable but evaluable, disease per RECIST v1.1
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy #6 months
- Creatinine clearance #60 milliliter per minute (mL/min) (calculated through use of the Cockcroft-Gault formula)

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study
- Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term appropriate for treatment with cytotoxic chemotherapy at time of entry into the study, as per national or local treatment guidelines
- Five or more prior lines of systemic therapy in the locally advanced or metastatic setting
- Treatment with anti-cancer therapies, including investigational therapies, within 28 days or 5 drug elimination half-lives, whichever is shorter, prior to initiation of study drug
- Treatment with an approved oral endocrine therapy within 7 days prior to initiation of study drug or treatment with fulvestrant or an approved/investigational CDK inhibitor within 21 days prior to initiation of study drug
- History of Grade #3 adverse event attributed to prior CDK inhibitor therapy that resulted in permanent discontinuation of prior CDK inhibitor therapy
- Poor peripheral venous access
- Malabsorption condition or other gastrointestinal (GI) conditions/surgeries that the investigator assesses may significantly interfere with enteral absorption
- Major surgical procedure within 28 days prior to initiation of study drug
- Untreated, active CNS metastases
- Infection requiring systemic (i.e., oral, IV, or intramuscular) antibiotics, chronic infection requiring treatment within 1 year prior to screening, or any evidence of current infection
- History of malignancy within 3 years prior to screening, except for cancer under investigation in this study
- Known history of a clinically significant abnormal ECG