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	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07214662 GO46057

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 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	Age	Healthy Volunteers
All	#18 Years	No

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