

Metastatic Breast Cancer

A Study to Evaluate the Effects of GDC-4198 in Combination With Letrozole, Fulvestrant, or Giredestrant in Participants With Locally Advanced or Metastatic Hormone Receptor-Positive, HER2-Negative Breast Cancer

Trial Status Not yet recruiting	Trial Runs In	Trial Identifier NCT07867262 2026-525266-22-00 GO46022
---	----------------------	---

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 Ib, Multicenter, Open-Label Study Evaluating the Safety, Pharmacokinetics, and Activity of GDC-4198 in Combination With Letrozole, Fulvestrant, or Giredestrant in Patients With Locally Advanced or Metastatic Hormone Receptor-Positive, HER2-Negative Breast Cancer Who Are Sensitive or Resistant to Endocrine Therapy

Trial Summary:

The study will evaluate the safety, pharmacokinetics, and preliminary activity of GDC-4198 when given in combination with endocrine therapy (ET) (letrozole, fulvestrant, or giredestrant) as first-line treatment to participants with locally advanced or metastatic Hormone receptor (HR)-positive, Human epidermal growth factor receptor-2 (HER2)-negative breast cancer

Genentech, Inc. Sponsor	Phase 1 Phase
NCT07867262 2026-525266-22-00 GO46022 Trial Identifiers	

Eligibility Criteria:

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

Inclusion Criteria:

ForPatients

by Roche

- Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and HER2-negative disease.
- Disease documented HER2-negative tumor according to American Society of Clinical Oncology/ College of American Pathologists (ASCO/CAP) guidelines or documented ER-positive tumor according to ASCO/CAP guidelines.
- Measurable and/or non-measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1) (including bone-only disease).
- For females ≤ 60 years of age who are not in a postmenopausal state and males: initiation of treatment with luteinizing hormone-releasing hormone (LHRH) agonist therapy prior to initiation of study treatment according to clinical practice for the selected agent (preferably at least 14 days prior to initiation of study treatment), and agreement to continue LHRH agonist therapy for the duration of the study. LHRH agonist therapy may be discontinued in women > 60 years of age.
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1.
- Life expectancy ≥ 6 months.
- Participants with Endocrine therapy (ET)-resistant disease and ET-sensitive disease as defined in the protocol.

Exclusion Criteria:

- Advanced, symptomatic, visceral spread at the time of study entry that is at risk of life-threatening complications and for which treatment with cytotoxic chemotherapy is considered appropriate per local treatment guidelines.
- Symptomatic, untreated, or actively progressing CNS metastases.
- History of systemic anti-cancer therapy for unresectable locally advanced breast cancer or metastatic breast cancer.
- Malabsorption condition or other gastrointestinal (GI) conditions/surgeries that the investigator assesses may significantly interfere with enteral absorption.
- History of malignancy within 3 years prior to screening, except for cancer under investigation in this study and malignancies with a negligible risk of metastasis or death.
- Known allergy or hypersensitivity to any component of the study treatments.