ForPatients
by Roche

Breast Cancer

A Study to Evaluate the Effect of GDC-4198 Alone and in Combination With Giredestrant Versus Abemaciclib and Giredestrant in Participants With Locally Advanced or Metastatic Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor-Negative (HER2-) Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	NCT07100106 2025-521128-31-00 2025 GO46021

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/II Multicenter, Open-Label, Randomized Study Evaluating the Safety, Pharmacokinetics, and Activity of GDC-4198 Alone and in Combination With Giredestrant in Comparison With Abemaciclib and Giredestrant in Participants With Locally Advanced or Metastatic Estrogen Receptor-Positive, HER2-Negative Breast Cancer Who Have Previously Progressed During or After a CDK4/6 Inhibitor

Trial Summary:

The purpose of this study is to assess the safety of GDC-4198 alone and in combination with giredestrant and also the efficacy of GDC-4198 + giredestrant versus abemaciclib + giredestrant in participants with locally advanced or metastatic ER+, HER2- breast cancer. The study consists of 2 phases: Phase Ib and Phase II. Phase Ib will evaluate the safety and pharmacokinetics (PK) of GDC-4198 alone and in combination with giredestrant. Phase II stage will compare the activity and safety of GDC-4198 and giredestrant with abemaciclib and giredestrant.

Genentech, Inc.
Sponsor

Phase 1/Phase 2
Phase

NCT07100106 2025-521128-31-00 2025 GO46021
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

Inclusion Criteria:

- Histologically and/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 after treatment with an approved cyclin-dependent kinase 4/6 (CDK4/6) inhibitor and approved endocrine therapy (ET) in the locally advanced or metastatic setting.
- Measurable or non-measurable evaluable, disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1).
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1.
- Life expectancy >= 6 months.

Exclusion Criteria:

- 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.
- Have received more than one-line of therapy for locally advanced or metastatic disease.
- Have received prior chemotherapy for metastatic breast cancer.
- Treatment with an approved oral ET within 7 days prior to initiation of study drug; treatment with fulvestrant or an approved CDK4/6 inhibitor within 21 days prior to initiation of study drug.
- 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.

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