ForPatients
by Roche

Breast Cancer

A study to compare the study medicine (GDC-0810) to another treatment (fulvestrant) in patients with breast cancer

A Study of GDC-0810 Versus Fulvestrant in Postmenopausal Women With Advanced or Metastatic Breast Cancer Resistant to Aromatase Inhibitor (AI) Therapy

Trial Status	Trial Runs In	Trial Identifier
Terminated	6 Countries	NCT02569801 2015-000106-19 GO29689

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 II, Open-Label, Randomized Study of GDC-0810 Versus Fulvestrant in Postmenopausal Women With Advanced or Metastatic ER+ /HER2- Breast Cancer Resistant to Aromatase Inhibitor Therapy

Trial Summary:

The primary purpose of this study is to evaluate the efficacy, safety, and tolerability of GDC-0810 compared with fulvestrant in postmenopausal women with advanced or metastatic estrogen receptor positive (ER+)/ human epidermal growth factor receptor 2 negative (HER2-) breast cancer resistant to AI therapy. The development of GDC-0810 has been halted by the Sponsor and the enrollment in this study has been discontinued. Participants currently enrolled in the study who are experiencing clinical benefit may continue receiving GDC-0810 as a single agent or fulvestrant until disease progression (PD), unmanageable toxicity, withdrawal of consent, exhaustion of GDC-0810 drug supply, or termination of the study by the Sponsor.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT02569801 2015-000106-19 GO29689
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years	No

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This clinical trial was done to study a new medicine called, “GDC-0810”. Researchers wanted to find out how effective GDC-0810 was for patients with ER+/HER2- breast cancer, in comparison to an approved treatment (fulvestrant). Seventy-one patients took part in this study at 26 study centers in 6 countries.

Inclusion Criteria:

- Postmenopausal women with histologically or cytologically confirmed invasive, ER+/HER- (defined by local guidelines) metastatic or inoperable, locally advance breast cancer
- Participants for whom endocrine therapy is recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study
- Participants must have measurable disease by RECIST v1.1 or non-measurable, evaluable disease with atleast one evaluable bone lesion by RECIST v1.1 based on radiologic scans within 28 days of Day 1 of Cycle 1
- Participants with radiologic/objective evidence of breast cancer recurrence or progression while on or within 6 months after the end of adjuvant treatment with an AI, or progression while on or within 1 month after the end of prior AI treatment for locally advanced or metastatic breast cancer

Exclusion Criteria:

- HER2-positive disease
- Prior treatment with fulvestrant
- Prior treatment with greater than (>) 1 cytotoxic chemotherapy regimen or >2 endocrine therapies for advanced or metastatic disease