ForPatients
by Roche

Breast Cancer

Study of a new medicine called “GDC-0927” in women who have a certain kind of breast cancer

A Study of GDC-0927 in Postmenopausal Women With Locally Advanced or Metastatic Estrogen Receptor Positive Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT02316509 2015-000272-95 GO29656

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:

An Open-Label, Phase I Study of GDC-0927 in Postmenopausal Women With Locally Advanced or Metastatic Estrogen Receptor Positive Breast Cancer

Trial Summary:

This is an open-label, dose-finding, safety, pharmacokinetics (PK), and evidence-of-activity study of GDC-0927 in postmenopausal women with locally advanced or metastatic Estrogen Receptor Positive (ER+) Human Epidermal Growth Factor Receptor 2 (HER2) breast cancer. The study will be conducted in two parts: Dose escalation and Dose expansion. During dose escalation, GDC-0927 will be administered orally as a single dose on Day -7 for PK evaluation during the lead-in period. Depending on safety and tolerability, participants will be assigned sequentially to escalating doses of GDC-0927 using standard 3+3 design. During dose expansion, there will be no PK week lead-in period. All participants will be treated until disease progression, unacceptable toxicity, participant withdrawal of consent or study termination.

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT02316509 2015-000272-95 GO29656
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-0927”. Researchers wanted to find out what the highest dose of GDC-0927 was that was safe for patients with ER+/HER- breast cancer. Researchers also wanted to investigate GDC-0927 doses in order to be able to recommend a safe dose that could be used in future studies. Forty-two patients took part in this study at 14 study centers in 2 countries.

Inclusion Criteria:

- Histologically or cytologically proven diagnosis of adenocarcinoma of the breast with evidence of either locally recurrent disease not amenable to resection or radiation therapy with curative intent, or metastatic disease, both progressing after at least 6 months of hormonal therapy for ER+ breast cancer
- ER-positive tumor, HER2-negative breast cancer
- No prior treatment with GDC-0810 (allowed only during dose expansion stage)
- No more than 2 prior chemotherapies in the advanced or metastatic setting
- At least 2 months must have elapsed from the use of tamoxifen
- At least 6 months must have elapsed from the use of fulvestrant
- At least 2 weeks must have elapsed from the use of any other endocrine therapy
- At least 3 weeks must have elapsed from the use of any chemotherapy
- Females, 18 years of age or older
- Postmenopausal status as defined by the protocol
- Eastern Cooperative Oncology Group (ECOG) Performance status less than or equal to (</=) 2 (for dose-escalation part) and 0 or 1 (for dose-expansion part)
- Adequate organ function

Exclusion Criteria:

- Untreated or symptomatic brain metastases
- Current treatment with any systemic anti-cancer therapies for advanced disease or any systemic experimental treatment on another clinical trial
- Any of the following within 12 months prior to enrollment: myocardial infarction, severe/unstable angina, ongoing cardiac dysrhythmias of Grade greater than or equal to (>/=) 2, atrial fibrillation of any grade, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, or cerebrovascular accident including transient ischemic attack
- Active inflammatory bowel disease or chronic diarrhea, short bowel syndrome, or upper gastrointestinal surgery including gastric resection
- Known Human Immunodeficiency Virus (HIV) infection
- Major surgery within 4 weeks prior to enrollment
- Radiation therapy within 2 weeks prior to enrollment