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 source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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. Sponsor	**Phase 1** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	>=18 Years	No

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.