ForPatients
by Roche

Breast CancerBreast NeoplasmsTumor

A study to compare “ipatasertib + chemotherapy” with “placebo + chemotherapy” – in patients with inoperable or metastatic triple negative breast cancer

A Study Assessing the Safety and Efficacy of Adding Ipatasertib to Paclitaxel Treatment in Participants With Breast Cancer That Has Spread Beyond the Initial Site, and the Cancer Does Not Have Certain Hormonal Receptors

Trial Status	Trial Runs In	Trial Identifier
Completed	8 Countries	NCT02162719 2014-000469-35 GO29227

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 Randomized, Phase II, Multi-Center, Placebo-Controlled Study of Ipatasertib (GDC-0068), an Inhibitor of Akt, in Combination With Paclitaxel as Front-Line Treatment for Patients With Metastatic Triple-Negative Breast Cancer

Trial Summary:

This multicenter, randomized, double-blind study will estimate the efficacy, safety and tolerability of ipatasertib combined with paclitaxel compared with placebo combined with paclitaxel in participants with inoperable locally advanced or metastatic triple-negative breast cancer (mTNBC), as measured by progression-free survival (PFS) in all participants and in participants with phosphatase and tensin homolog (PTEN)-low tumors.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT02162719 2014-000469-35 GO29227
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, “ipatasertib”, for the treatment of patients with “triple negative breast cancer” or “TNBC” for short. This study was done to find out if adding ipatasertib to chemotherapy improved the outcome for patients with TNBC. Researchers also wanted to know the effect of ipatasertib on patients with TNBC who had certain genetic mutations. One hundred and twenty-four patients took part in this study at 69 study centers in eight countries.

Inclusion Criteria:

- Histologically documented triple-negative adenocarcinoma of the breast that is inoperable locally advanced or metastatic and is not amenable to resection with curative intent
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen, required prior to randomization
- Measurable disease, according to the RECIST v1.1
- Adequate hematologic and organ function within 14 days before the first study treatment
- For female participants of childbearing potential, agreement (by both participant and partner) to use an effective form of contraception for the duration of the study and for 6 months after last dose of study treatment

Exclusion Criteria:

- Any previous therapy, including chemotherapy or hormonal or targeted therapy, for inoperable locally advanced or metastatic triple-negative adenocarcinoma of the breast. Participants may have received prior neoadjuvant or adjuvant chemotherapy and/or radiation treatment for locally advanced triple negative adenocarcinoma, provided all treatments were completed greater than or equal to (>/=) 6 months prior to Cycle 1 Day 1. Locally recurrent disease must not be amenable to resection with curative intent
- Any radiation treatment to metastatic site within 28 days of Cycle 1, Day 1
- Known Human Epidermal Growth Factor Receptor 2 (HER2) positive, erythrocyte receptor (ER) positive, or progesterone receptor (PR) positive breast cancer
- Previous therapy with Akt, PI3K, and/or mTOR inhibitors
- Major surgical procedure, open biopsy, or significant traumatic injury within 30 days prior to Cycle 1, Day 1 or anticipation of need for a major surgical procedure during the course of the study
- Known presence of the brain or spinal cord metastasis, as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening or prior radiographic assessments