

Breast Cancer

A Study of Taselisib + Fulvestrant Versus Placebo + Fulvestrant in Participants With Advanced or Metastatic Breast Cancer Who Have Disease Recurrence or Progression During or After Aromatase Inhibitor Therapy

Trial Status
Terminated

Trial Runs In
28 Countries

Trial Identifier
NCT02340221 2014-003185-25
GO29058

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 international, multicenter, randomized, double-blinded, placebo-controlled study is designed to compare the efficacy and safety of taselisib + fulvestrant with that of placebo + fulvestrant in postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative, oncogene that encodes for phosphatidylinositol-4,5-bisphosphate 3-kinase (PIK3CA)-mutant, unresectable, locally advanced or metastatic breast cancer after recurrence or progression during or after an aromatase inhibitor (AI) therapy. There will be a 2:1 randomization to the taselisib arm versus the placebo arm. Enrollment will be enriched for participants with PIK3CA mutant tumors via central testing. The anticipated duration of the study is approximately 3.5 years.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
Female

Age
>=18 Years

Healthy Volunteers
No
