ForPatients
by Roche

Breast Cancer

To Study the Effect of Inavolisib in Combination With Fulvestrant in Participants With Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07368998 2025-522805-39-00 WO46063

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, Randomized, Open-Label Study Evaluating Two Inavolisib Dose Levels in Combination With Fulvestrant in Participants With PIK3CA-Mutated, HR-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of inavolisib in combination with fulvestrant compared with inavolisib in combination with fulvestrant in participants with PIK3CA-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer (LA/mBC) in the post-cyclin-dependent kinase inhibitor (CDKi) setting.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Documented ER +/ HER2- tumor according to American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines
- Disease progression after or during treatment with a combination of CDK4/6i and endocrine therapy: <= 1 prior lines of systemic therapy in the locally advanced (recurrent or progressed) or metastatic setting

- Measurable or evaluable disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)
- Participants for whom endocrine-based therapy is recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study, as per national or local treatment guidelines
- Confirmation of biomarker eligibility: presence of >= 1 study-eligible PIK3CA mutation
- Life expectancy of > 6 months
- Ability, in the investigator's judgment, and willingness to comply with all study -related procedures, including completion of patient-reported outcomes

Exclusion Criteria:

- Metaplastic breast cancer
- Prior treatment with chemotherapy in the recurrent locally advanced/metastatic setting
- Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes
- Prior treatment with PI3K/Akt/mTOR inhibitors in the recurrent locally advanced/metastatic setting
- Requirement for daily supplemental oxygen
- Symptomatic active lung disease, including pneumonitis