ForPatients
by Roche

Breast Cancer

A Study to Test Inavolisib Treatments in Participants With Early-Stage, PIK3CA-Mutated Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07054190 2024-518811-20-00 BO45853

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, Open-Label, Multicenter Study Evaluating the Safety and Efficacy of Neoadjuvant Treatment With Inavolisib Combinations in Patients With Untreated, Early-stage, PIK3CA-Mutated Breast Cancer

Trial Summary:

This study will evaluate the safety and efficacy of inavolisib combination therapies in participants with untreated, PIK3CA-mutated, Stage II-III, estrogen receptor (ER)-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-negative breast cancer (BC).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years	No

Inclusion Criteria:

- Histologically confirmed operable or inoperable invasive Stage II-III BC according to American Joint Committee on Cancer (AJCC) TNM staging classification
- Candidate for neoadjuvant treatment and considered appropriate for endocrine combination therapy
- Willingness to undergo breast surgery (mastectomy or breast-conserving surgery) after neoadjuvant treatment (unless inoperable)
- Documented ER-positive tumor in accordance with current American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines

- Documented HER2-negative tumor in accordance with current ASCO/CAP guidelines
- Documented Ki-67 score >=5% as per local assessment
- Confirmed PIK3CA mutation

Exclusion Criteria:

- Stage IV (metastatic) BC
- Inflammatory BC (cT4d)
- Bilateral invasive BC
- History of ductal carcinoma in situ or lobular carcinoma in situ if they have received any systemic therapy for treatment or radiation therapy to the ipsilateral breast
- Previous systemic or local treatment for the primary BC currently under investigation (including excisional biopsy or any other surgery of the primary tumor and/or axillary lymph nodes, including sentinel lymph node biopsy, radiotherapy, cytotoxic, and endocrine treatments)
- Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes