A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING THE EFFICACY AND SAFETY OF INAVOLISIB PLUS A CDK4/6 INHIBITOR AND LETROZOLE VERSUS PLACEBO PLUS A CDK4/6 INHIBITOR AND LETROZOLE IN PATIENTS WITH ENDOCRINE-SENSITIVE PIK3CA-MUTATED, HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE ADVANCED BREAST CANCER (WO45654)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- women or men with confirmed breast cancer - ER-positive and/or progesterone receptor-positive and HER2-negative tumor - may not be able to do strenuous activity but able to walking and carry out work of a light or sedentary nature, e.g., light house work, office work - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- women who are pregnant, breastfeeding, or intend to become pregnant - metaplastic breast cancer - Type 2 diabetes requiring ongoing treatment; or any history of Type 1 diabetes - inflammatory or infectious conditions in either eye - active lung disease - history of or active inflammatory bowel disease - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Drug: CDK4/6i, Drug: Inavolisib, Drug: Letrozole, Drug: Placebo
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), breast cancer

More Information

Description: The purpose of this research is to test safety, efficacy and compare the effects of a combination therapy involving inavolisib plus a CDK4/6i (palbociclib) and letrozole versus placebo plus a CDK4/6i (palbociclib) and letrozole on patients with HR+, HER2- advanced breast cancer (ABC). In this study, you will get either inavolisib plus palbociclib and letrozole or placebo plus palbociclib and letrozole. A placebo looks like a drug but has no active ingredient.
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