

A Phase 1b Open-Label Multicenter Study of OP-1250 (Palazestrant) in Combination with the CDK4/6 Inhibitor Ribociclib, with the PI3K Inhibitor Alpelisib, or with the mTOR inhibitor Everolimus in Adult Subjects with Advanced and/or Metastatic ER Positive, HER2 Negative Breast Cancer

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 18 years old - diagnosis of advanced and/or Metastatic HR Positive, HER2 Negative Breast Cancer - received no more than 2 prior hormonal regimens for advanced or metastatic disease - received no more than 1 prior chemotherapy for locally advanced or metastatic breast cancer

Exclusion Criteria:

- significant heart disease - cerebral vascular disease within 6 months - pulmonary embolism, or deep venous thrombosis within the last 6 months - pneumonitis or interstitial lung disease - history or ongoing gastrointestinal disorders that result in poor absorption of medications - history of significant liver disease - study staff will review medical history

Conditions & Interventions

Interventions:

Drug: Alpelisib, Drug: OP-1250, Drug: Ribociclib

Conditions:

Cancer

Keywords:

Clinics and Surgery Center (CSC), alpelisib, HER2-neg breast cancer, HR-positive Breast Cancer, Metastatic Breast cancer, ribociclib

More Information

Description: The main purpose of this study is to look at how safe and well tolerated the study drug is in combination with ribociclib (Group 1) or alpelisib (Group 2), the levels of the study drug and ribociclib or alpelisib in your blood, and how your body and your cancer respond.

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