A Study to Evaluate Efficacy and Safety of Giredestrant Compared With Fulvestrant (Plus a CDK4/6 Inhibitor), in Participants With ER-Positive, HER2-Negative Advanced Breast Cancer Resistant to Adjuvant Endocrine Therapy (pionERA Breast Cancer)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Locally advanced or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent * Documented estrogen receptor-positive (ER+), HER2-negative (HER2-) tumor assessed locally on the most recent tumor biopsy (or an archived tumor sample if a recent tumor sample is not available for testing) * Confirmed ESR1 mutation status (ESR1m versus ESR1nmd) in baseline circulating tumor DNA (ctDNA) through central laboratory testing * Resistance to prior adjuvant endocrine therapy (ET), which is defined as having relapsed with prior standard adjuvant ET, on-treatment after \>/=12 months or off-treatment within 12 months of completion. Prior use of adjuvant CDK4/6i is allowed (if relapse occurred \>/=12 months since completion). * No prior systemic anti-cancer therapy for advanced disease * Measurable disease as defined per RECIST v.1.1 or non-measurable (including bone-only) disease * Eastern Cooperative Oncology Group Performance Status (ECOG PS) 0-1 * For pre/perimenopausal women and for men: willing to undergo and maintain treatment with approved LHRH agonist therapy (as per local guidelines) for the duration of study treatment

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Exclusion Criteria:

* Prior systemic therapy (e.g., prior chemotherapy, immunotherapy, or biologic therapy) for locally advanced unresectable or metastatic breast cancer * Prior treatment with another SERD (e.g., fulvestrant, oral SERDs) or novel ER-targeting agents * Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term * Active cardiac disease or history of cardiac dysfunction * Clinically significant history of liver disease

Conditions & Interventions

Interventions:
DRUG: Giredestrant, DRUG: Fulvestrant, DRUG: Abemaciclib, DRUG: Palbociclib, DRUG: Ribociclib, DRUG: LHRH Agonist, DIAGNOSTIC_TEST: FoundationOne Liquid CDx Assay (F1LCDx)
Conditions:
Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer
Keywords:
oral Selective Estrogen Receptor Degrader (SERD), CDK4/6 inhibitor (CDK4/6i), ESR1 mutation

More Information

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Phase: PHASE3
IRB
Number:
System ID: NCT06065748
