ForPatients
by Roche

Breast Cancer Er-PositiveBreast CancerBreast Neoplasms

A Study of Multiple Immunotherapy-Based Treatment Combinations in Hormone Receptor (HR)-Positive Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03280563 2017-000335-14 CO39611

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 Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Hormone Receptor-Positive HER2-Negative Breast Cancer (MORPHEUS-HR+ Breast Cancer)

Trial Summary:

This study is designed to evaluate the efficacy, safety, and pharmacokinetics of several immunotherapy-based combination treatments in participants with inoperable locally advanced or metastatic HR-positive, HER2-negative breast cancer who have progressed during or following treatment with a cyclin-dependent kinase (CDK) 4/6 inhibitor in the first- or second-line setting, such as palbociclib, ribociclib, or abemaciclib. The study will be performed in two stages. During Stage 1, participants will be randomized to fulvestrant (control) or an atezolizumab-containing doublet or triplet combination. Those who experience disease progression, loss of clinical benefit, or unacceptable toxicity may be eligible to receive a new triplet combination treatment in Stage 2 until loss of clinical benefit or unacceptable toxicity. New treatment arms may be added and/or existing treatment arms may be closed during the course of the study on the basis of ongoing clinical efficacy and safety as well as the current treatments available.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT03280563 2017-000335-14 CO39611
Trial Identifiers

Eligibility Criteria:

ForPatients
by Roche

Gender	Age	Healthy Volunteers
Female	**# 18 Years**	**No**

Inclusion Criteria:

Inclusion Criteria for Both Stages:

- Measurable disease per RECIST v1.1
- Adequate hematologic and end organ function
- Disease progression during or after first- or second-line hormonal therapy with CDK4/6 inhibitor

Inclusion Criteria for Stage 1:

- Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- Metastatic or inoperable, locally advanced, histologically or cytologically confirmed invasive HR-positive HER2-negative breast cancer
- Recommended for endocrine therapy, and cytotoxic chemotherapy not indicated at study entry
- Recurrence or progression following most recent systemic breast cancer therapy
- Disease progression during or after first- or second-line hormonal therapy for locally advanced or metastatic disease
- Postmenopausal according to protocol-defined criteria
- Life expectancy >3 months
- Available tumor specimen for determination of PD-L1 status

Inclusion Criteria for Stage 2:

- ECOG performance status of 0-2
- Ability to initiate treatment within 3 months after disease progression or unacceptable toxicity on a Stage 1 regimen

Exclusion Criteria:

Exclusion Criteria for Both Stages:

- Significant or uncontrolled comorbid disease as specified in the protocol
- Uncontrolled tumor-related pain
- Autoimmune disease except for stable/controlled hypothyroidism, Type 1 diabetes mellitus, or certain dermatologic conditions
- Positive human immunodeficiency virus test
- Active hepatitis B or C
- Active tuberculosis
- Severe infection within 4 weeks and/or antibiotics within 2 weeks prior to study treatment
- Prior allogeneic stem cell or solid organ transplantation
- History of malignancy other than breast cancer within 2 years prior to screening except those with negligible risk of metastasis/death
- History of or known hypersensitivity to study drug or excipients
- For patients entering Stage 2, recovery from all immunotherapy-related adverse events to Grade 1 or better or to baseline at the time of consent

Exclusion Criteria for Stage 1:

- Prior fulvestrant or cytotoxic chemotherapy for metastatic breast cancer, or certain other agents as specified in the protocol
- Unresolved AEs from prior anti-cancer therapy
- Eligibility only for the control arm
- Prior treatment with inhibitors as specified in the protocol

Exclusion Criteria for Stage 2:

- Unacceptable toxicity with atezolizumab during Stage 1
- Uncontrolled cardiovascular disease or coagulation disorder, including use of anticoagulants as specified in the protocol
- Significant abdominal or intestinal manifestations within 6 months prior to treatment
- Grade 2 or higher proteinuria