A Study of SHR6390 in Combination With Fulvestrant in Patients With HR Positive and HER2 Negative Advanced Breast Cancer

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03927456	ACTIVE, NOT RECRUITING	APRIL 25, 2019	JUNE 3, 2021

STUDY DESCRIPTION

Brief Summary

This is a phase III clinical trial to evaluate the efficacy and safety of SHR6390 in combination with Fulvestrant versus placebo combined with Fulvesrant in Patients who have HR positive and HER2 negative recurrent/metastatic breast cancer and have received prior endocrine therapy are eligible for study.

Condition or Disease: Advanced Breast Cancer

Intervention/treatment: Drug: SHR6390
Drug: Placebo
Drug: Fulvestrant

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 357 participants

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Phase III Study to Evaluate the Efficacy and Safety of SHR6390 in Combination With Fulvestrant Versus Placebo Combined With Fulvesrant in Patients With HR Positive and HER2 Negative Recurrent/Metastatic Breast Cancer

Actual Study Start Date: June 2019

Estimated Primary Completion Date: December 2021

Estimated Study Completion Date: December 2022

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: SHR6390 + Fulvestrant Intervention Drug: SHR6390, Fulvestrant	Drug: SHR6390 SHR6390 150 mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment Drug: Fulvestrant Fulvestrant 500mg intramuscular injection on day 1 and day 15 for the first cycle and then on day 1 for every cycle until progressive disease
Placebo Comparator: Placebo + Fulvestrant Intervention Drug: Placebo, Fulvestrant	Drug: Placebo Placebo 150 mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment Drug: Fulvestrant Fulvestrant 500mg intramuscular injection on day 1 and day 15 for the first cycle and then on day 1 for every cycle until progressive disease

OUTCOME MEASURES

Primary Outcome Measures: 1. Investigator-assessed PFS [Time Frame: Up to approximately 24 months.]
Investigator-assessed Progression Free Survival

Secondary Outcome Measures:
1. Progression-free Survival (PFS) per RECIST 1.1 [Time Frame: Up to approximately 24 months.]
PFS is defined as the time from randomization to the first documented disease progression per RECIST 1.1 based on blinded independent central review or death due to any cause, whichever occurs first.
2. OS [Time Frame: Up to approximately 2 years]
Overall Survival
3. ORR [Time Frame: Up to approximately 24 months.]
Objective Response Rate
4. DoR [Time Frame: Up to approximately 24 months]
Duration of Objective Response
5. CBR [Time Frame: Up to approximately 24 months.]
Clinical Benefit rate

6. AEs and SAEs [Time Frame: Up to approximately 24 months.]
Number of Participants With adverse events (AEs) and serious adverse events (SAEs) Incidence, nature, and severity of adverse events graded according to the NCI CTCAE v4.03.
7. Ctrough [Time Frame: Up to 4 weeks]
Ctrough

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 75 Years (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Has the pathologically-confirmed diagnosis of locally recurrent or metastatic, hormone-receptor positive, HER2 negative Breast Cancer.
2. Age: 18 - 75 years old, postmenopausal women or prepostmenopausal women
3. Received prior endocrine therapy
4. One previous line of chemotherapy for advanced/metastatic disease is allowed in addition to endocrine therapy.
5. Eastern Cooperative Oncology Group [ECOG] 0-1
Exclusion Criteria:
1. Patients who received prior treatment with any CDK4/6 inhibitor, everolimus or fulvestant.
2. Clinically significant cardiovascular and cerebrovascular diseases,including but not limited to severe acute myocardial infarction within 6 months before enrollment, unstable or severe angina, Congestive heart failure (New York heart association (NYHA) class > 2), or ventricular arrhythmia which need medical intervention.

CONTACTS AND LOCATIONS

Contacts

Locations

China, Beijing	Chinese Academy of Medical Science	Beijing

Sponsors and Collaborators

Jiangsu HengRui Medicine Co., Ltd.

Investigator

MORE INFORMATION

Responsible Party :	Jiangsu HengRui Medicine Co., Ltd.
ClinicalTrials.gov Identifier :	NCT03927456
Other Study ID Numbers :	SHR6390-III-301
First Posted :	April 25, 2019
Last Update Posted :	June 3, 2021
Last Verified :	June 2020
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms :	*Breast Neoplasms*