SERENA-6

TRIAL TITLE

Phase III Study to Assess AZD9833 + CDK4/6 Inhibitor in HR+/HER2-MBC With Detectable ESR1m Before Progression (SERENA-6)

TRIAL STATUS

Active, not recruiting

TRIAL NUMBER

NCT04964934

TRIAL PHASE

Phase 3

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Adults 18 or older with advanced breast cancer (metastatic breast cancer) who could not be treated with surgery or radiation.
- Had hormone receptor-positive (HR+), HER2-negative (HER2-) breast cancer.
- Had an ESR1 mutation in their cancer.
- Had been taking a CDK4/6 inhibitor (like palbociclib, abemaciclib or ribociclib) with an aromatase inhibitor (like letrozole or anastrozole) for at least 6 months.
- Cancer must not have gotten worse after taking an aromatase inhibitor and CDK4/6 inhibitor treatment.
- Had no previous treatment with investigational selective estrogen receptor degraders (SERDs), fulvestrant or AZD9833.

*Additional eligibility criteria may have applied.

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TRIAL DETAILS:

- SERENA-6 is a randomized, triple-blind, multicenter Phase 3 clinical trial.
- The study includes approximately 315 randomized participants to determine if switching to AZD9833 (also known as camizestrant) and continuing a CDK4/6 inhibitor after detection of an ESR1 mutation can delay disease progression compared to continuing treatment on an aromatase inhibitor plus CDK4/6 inhibitor.
- Participants undergo routine blood tests to monitor for ESR1 mutations before the cancer progresses.
- Upon detection of an ESR1 mutation, participants are randomly assigned to receive either camizestrant, an oral medication taken once daily, or an aromatase inhibitor (anastrozole or letrozole) in combination with their existing CDK4/6 inhibitor treatment.
- The primary outcome being measured is how long participants live without their cancer worsening, also known as progression-free survival.

ABOUT HR+/HER2- METASTATIC BREAST CANCER, ESR1 MUTATIONS AND CAMIZESTRANT:

- HR+/HER2- metastatic breast cancers are currently treated with hormone therapy, like aromatase inhibitors, in combination with CDK4/6 inhibitors.
- ESR1 mutations are changes in the estrogen receptor gene that can develop during treatment with aromatase inhibitors, which lead to treatment resistance and reduced effectiveness of aromatase inhibitors.
- Camizestrant is an investigational oral SERD that is designed to block and degrade estrogen receptors, potentially overcoming the resistance that occurs with ESR1 mutations.
- This trial is testing whether switching to camizestrant at the point of ESR1 mutation detection, rather than progression on a scan, can extend the time before the cancer gets worse compared to staying on an aromatase inhibitor.

References:

1. AstraZeneca. Phase 3 study to assess AZD9833 plus CDK4/6 inhibitor in HR-positive/HER2-negative metastatic breast cancer with detectable ESR1 mutation before progression (SERENA-6) (NCT04964934). U.S. National Library of Medicine, ClinicalTrials.gov, July 16, 2021. https://clinicaltrials.gov/ct2/show/NCT04964934
2. Howell, S.J., Lin, Y., Gao, H., Yardley, D.A., Bardia, A., Mehta, R.S., et al. SERENA-6: A phase 3 study to assess switching to AZD9833 (camizestrant) plus CDK4/6 inhibitor versus continuing aromatase inhibitor in HR-positive/HER2-negative metastatic breast cancer with detectable ESR1 mutation. Future Oncology, vol. 19, no. 5, 2023, pp. 123–135. https://doi.org/10.2217/fon-2022-1196

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