Spotlight on Clinical Trials

VERITAC-2 Clinical Trial

TRIAL TITLE

A clinical trial to learn about a study medicine called vepdegestrant (ARV-471) in people who have advanced metastatic breast cancer (VERITAC-2)

STATUS

Recruiting

TRIAL NUMBER

NCT05654623

TRIAL PHASE

Phase 3

REFERENCES

1. Hormone Therapy for Metastatic Breast Cancer: https://www.komen.org/ https://www.komen.org/ https://www.komen.org/

If you are interested in learning more about VERITAC-2, visit www.veritac2study.com

KEY TRIAL DETAILS:

- Approximately 560 participants will be randomized to receive vepdegestrant (ARV-471) or fulvestrant.
- Vepdegestrant (ARV-471) is a tablet that is taken by mouth with food once daily, preferably in the morning.
- Fulvestrant is given as an injection twice a month for the first month, then once a month thereafter.
- The study will determine how safe vepdegestrant (ARV-471) is and if it works better than an approved therapy, fulvestrant, in prolonging the time without the disease getting worse in people with advanced breast cancer.

ABOUT METASTATIC ER-POSITIVE/ HER2-NEGATIVE BREAST CANCER AND VEPDEGESTRANT:

- People with metastatic ER-positive/ HER2-negative breast cancer are often treated with hormone therapy in combination with a CDK4/6 inhibitor. Once this treatment stops working, they can often switch to a different hormone therapy, the choice of which may depend on their cancer characteristics.¹
- Eventually, after all hormone therapy treatments are exhausted, chemotherapy can be considered.
- More treatment options are needed for people with advanced/ metastatic ER-positive/HER2negative breast cancer.
- Vepdegestrant is being tested as a potential hormone therapy for people with advanced/metastatic ER-positive, HER2-negative breast cancer whose disease has worsened after treatment with an hormone therapy and CDK4/6 inhibitor.

THIS STUDY IS OPEN TO PEOPLE WHO MEET THE FOLLOWING CRITERIA*:

- Are at least 18 years old and have been diagnosed with advanced breast cancer (i.e., locoregionally advanced or metastatic disease) that
 - Expresses estrogen receptors and is called ER-positive
 - Does not express a marker, human epidermal growth factor receptor 2 (HER2) and is called HER2negative
- Must have been treated with a CDK4/6 inhibitor in combination with hormonal therapy. CDK4/6 inhibitors include medications called palbociclib (IBRANCE®), ribociclib (KISQALI®) and abemaciclib (Verzenio®).
- May have been treated with 1 additional round of treatment with hormonal therapy (not required)
- Must have worsened during or after your last therapy
- Do not have a history of any tumor malignancies other than breast cancer within the past three years
- Do not have newly diagnosed brain metastasis or symptomatic central nervous system metastases, carcinomatous meningitis, or leptomeningeal disease
- Do not have inflammatory breast cancer
- Do not have clinically significant heart (cardiovascular) disease
- Do not have kidney (renal) impairment, not adequate liver function and/or bone marrow function

*Additional eligibility criteria apply

