

Vepdegestrant (ARV-471), a PROTAC[®] ER degrader, or anastrozole in postmenopausal women with ER+/HER2- localized breast cancer

This summary contains information from the scientific poster:

TACTIVE-N: open-label, randomized, noncomparative neoadjuvant phase 2 study of ARV-471, a PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, or anastrozole in postmenopausal women with ER+/human epidermal growth factor receptor 2 (HER2)- localized breast cancer

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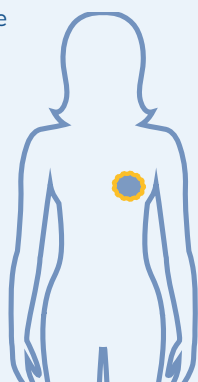
What is ER+/HER2- localized breast cancer?

ER+/HER2- breast cancer is one type of breast cancer

- Certain types of breast cancer grow in response to **estrogen**, a hormone (or **chemical messenger**) in your body. This is called **estrogen receptor-positive (ER+)** breast cancer
- Some types of breast cancer have a lot of a protein called **human epidermal growth factor receptor 2 (HER2)** and are called **HER2-positive (HER2+)**. Other breast cancer types have low levels or no HER2 and are called **HER2-negative (HER2-)**

Localized breast cancer is cancer that is present only within breast tissue. It can often be removed through breast cancer surgery

- This is different from cancer that has spread from the breast to nearby tissue (**locally advanced cancer**) or from the breast to more distant parts of the body (**metastatic cancer**)



What is neoadjuvant therapy for breast cancer?

Women with localized breast cancer might receive preoperative (or **neoadjuvant**) therapy to **shrink the size of the tumor** prior to surgery

What are the different types of neoadjuvant treatments for ER+/HER2- localized breast cancer?

Some treatments, called **endocrine therapies**, work by either blocking the body's ability to produce hormones, such as estrogen, or blocking the activity of these hormones in cancer cells. This may slow or stop cancer growth

- **Aromatase inhibitors**, such as anastrozole, are endocrine therapies that reduce the production of estrogen

Chemotherapy is a treatment that damages cancer cells

What is vepdegestrant?

Vepdegestrant, also called **ARV-471**, is an investigational drug that is being evaluated as a treatment for ER+ breast cancer. It is a **PROteolysis TArgeting Chimera (PROTAC) protein degrader that binds to estrogen receptors**

- PROTAC protein degraders are designed to bind specific proteins of interest in cells, which causes those proteins to be **marked for elimination** by a natural protein disposal system in the body
- Vepdegestrant works by causing **estrogen receptors to be eliminated**, which blocks the activity of estrogen and could potentially stop ER+ breast cancer tumors from growing or cause the tumors to shrink

A **clinical study that tested different doses of vepdegestrant** in people with ER+/HER2- **advanced breast cancer** showed that, during the study, vepdegestrant could slow or stop breast cancer growth in some people and that the **side effects of vepdegestrant were mostly mild or moderate**

This summary describes a clinical study to evaluate preoperative treatment with **vepedgestrant** or **anastrozole** in women with ER+/HER2- localized breast cancer

The **main aim** of this study is to evaluate

- Whether **vepedgestrant** or **anastrozole** can reduce the proliferation of breast cancer cells

This study also will look at

- The **side effects** women who take **vepedgestrant** or **anastrozole** may experience
- Whether **vepedgestrant** or **anastrozole** can cause tumors to stop growing or shrink before breast cancer surgery

Study Design

WHO CAN PARTICIPATE IN THE STUDY?



Postmenopausal women with **ER+/HER2- localized breast cancer** who also

- Have a tumor that is **at least 1.5 cm in size** and that can be operated on
- Have breast cancer expressing certain **tumor markers**
- Are **physically healthy** and able to do regular daily activities
- Are willing to undergo **breast cancer surgery** and provide **breast cancer samples (biopsies)** before the study and during treatment

WHO CANNOT PARTICIPATE IN THE STUDY?



- Women with breast cancer **in the milk ducts** or **breast cancer that has spread beyond the breast** to the chest, the skin of the breast, lymph nodes, or other areas of the body
- Women previously treated for **breast cancer**

WHAT IS THE TREATMENT?

- Participants will be **assigned at random** to receive **vepedgestrant** or **anastrozole**
- Vepedgestrant or anastrozole will be taken as a **pill once daily**
- After approximately **5.5 months of treatment**, participants will undergo breast cancer surgery

WHAT WILL BE MEASURED IN THE STUDY?

- The **proliferation of breast cancer cells after 2 weeks of vepedgestrant or anastrozole treatment**
 - This is measured by analyzing the **amount of a protein called Ki-67** in a breast cancer sample (biopsy). Ki-67 is a marker of cell growth and division
- The **side effects** experienced by women taking vepedgestrant or anastrozole
 - This includes any **symptoms** felt by the participants in the study, **signs** observed in the participants by the investigators, or **abnormalities** that are detected in the participants' blood samples
- **Tumor size and whether the tumor has spread** at the time of surgery will be measured to evaluate if vepedgestrant or anastrozole treatment has any effect on slowing tumor growth or shrinking tumors
- The number of women treated with vepedgestrant or anastrozole that were able to have their **breast conserved** during breast cancer surgery

Who sponsored this study?

This study is sponsored by **Arvinas Estrogen Receptor, Inc.**
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Where can I find more information?

For more information on **this study**

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