HERTHENA-Breast04

Learn about a clinical trial for people with **Metastatic Breast Cancer**

In this brochure, you will learn about HR+/HER2- unresectable locally advanced or metastatic breast cancer and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational trial drug is safe and may help stop or slow down the growth of this cancer among patients who have already received certain types of treatments, but their cancer has spread or cannot be removed with surgery. You can also use this brochure to talk with your doctor about this trial.

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What is metastatic HR+/HER2- breast cancer?

HR+/HER2- breast cancer is the most common type of breast cancer.

- HR+ (hormone receptor positive) means the breast cancer cells have proteins that attach to the hormones estrogen and/or progesterone, which can help cancer cells grow.

- HER2- (human epidermal growth factor receptor 2 negative) means the cancer cells do not make high levels of a protein called HER2. HER2- cancer cells grow and spread slower than HER2+ cancer cells.

When HR+/HER2- breast cancer is found early and treated, there is a low chance that it will come back. However, sometimes it comes back after treatment, starts to spread, and can't be removed by surgery.

What is unresectable locally advanced or metastatic cancer?

Locally advanced cancer means the cancer is in the early stages of spreading. Metastatic means the cancer has spread to other parts of the body. Some locally advanced or metastatic cancer is unresectable, meaning it cannot be removed by surgery.

What are my treatment options?

If you have unresectable locally advanced or metastatic breast cancer, your care team will talk about your treatment options with you and those close to you.

Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms

Your care team may offer you 1 or more of these treatments:

- **Local therapies** – treatment directed at the site of the cancer to destroy it
- **Targeted therapy** – treatment that works on specific cells to stop them from growing
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Palliative care** – also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat unresectable locally advanced or metastatic breast cancer, but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove part of the cancer. This would only be used to treat symptoms related to tumor growth.
- **Clinical trials**, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if the investigational trial drug patritumab deruxtecan (also called MK1022 or HER3-DXd) may help stop or slow down unresectable locally advanced or metastatic

HR+/HER2- breast cancer, compared to other anti-cancer treatments. Researchers are studying the investigational drug in people who have not had chemotherapy after the cancer became unresectable locally advanced or metastatic.

This trial is testing the investigational drug, patritumab deruxtecan, when given alone, and comparing it to 6 other treatments that are commonly used to treat this type of breast cancer. Patritumab deruxtecan is experimental. It has not been approved to treat unresectable locally advanced or metastatic HR+/HER2- breast cancer.

What treatment is being studied?

The investigational study medicine is called patritumab deruxtecan. The information below is what researchers assume to know about how the investigational trial drug may work.

About patritumab deruxtecan

Patritumab deruxtecan (also known as HER3-DXd) is a type of investigational targeted therapy known as an antibody drug conjugate (ADC) that may destroy cancer cells.

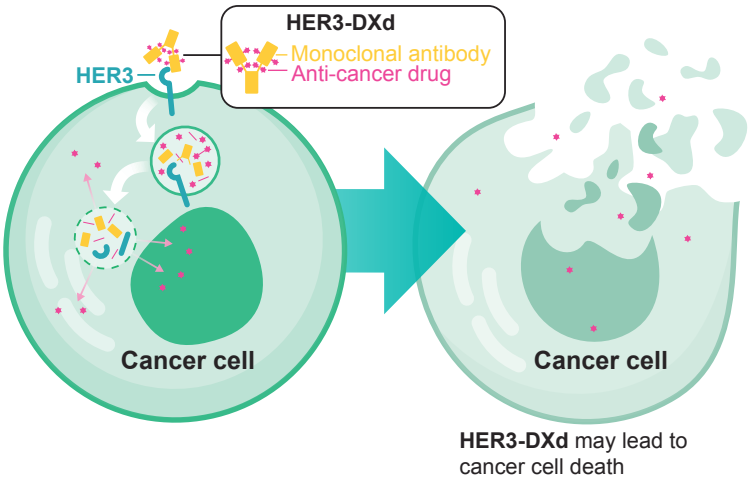
Unlike traditional chemotherapy, ADCs have 3 parts:

- **A monoclonal antibody:** A protein that binds to specific receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is HER3.
- **An anti-cancer drug:** A type of drug that may lead to cancer cell death.
- **Linker:** Connects the anti-cancer drug to the monoclonal antibody.

Another way to think about patritumab deruxtecan

1. HER3 receptors are involved in how cells in the body grow and survive. These receptors are more common in some cancer cells.
2. The monoclonal antibody in the investigational drug, patritumab deruxtecan, finds and binds to the HER3 receptor on cancer cells which brings it inside the cancer cells.

3. Once inside, patritumab deruxtecan breaks down and releases an anti-cancer drug that may lead to the cancer cell death.
4. The anti-cancer drug may get released from the targeted cancer cells and enter nearby cancer cells without HER3 and cause these cells to die as well.



Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation.

For example, you must:

- Have HR+/HER2- unresectable locally advanced or metastatic breast cancer
- Have had the cancer grow or spread during treatment with hormone therapy (a treatment that blocks the hormones that cancer cells use to grow)
- Have not had chemotherapy after the cancer became unresectable locally advanced or metastatic

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- What type of cancer you have
- How well you tolerate the study treatments

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the trial drug is working for you.

During your trial visits, you may get:

- Your trial treatment
- Blood and/or urine tests
- Physical exams
- Imaging scans such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)
- Questions about how you are feeling

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

What treatment will I get?

The treatment you get will depend on which group you are randomly placed in.

This trial has two groups:

- **Group 1** will get the investigational trial drug patritumab deruxtecan
- **Group 2** will get 1 of 6 common treatments for this type of breast cancer. You will discuss which treatment you will get with your trial doctor.

A computer will decide which group you are put in. You have an equal chance of getting put in each group.

You, your trial doctor, and the trial staff will know what trial drug you are getting.

Thank you for learning about metastatic breast cancer and this clinical trial

You can use this brochure to talk with your doctor about this trial.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit **www.merckclinicaltrials.com**
- Scan this QR code:

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For more information, contact our research staff: