HERTHENA-Breast01

Learn about a clinical trial for HER2-positive Breast Cancer

In this brochure, you will learn about HER2-positive (HER2+) locally advanced unresectable or metastatic breast cancer and a clinical trial for this disease. In this trial, researchers are trying to find out if investigational combinations of trial drugs are safe and may help slow down or stop the growth of this cancer.

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

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What is HER2-positive breast cancer?

Breast cancer is cancer that starts in your breast tissue. HER2-positive (or HER2+) means the cancer cells make high levels of a protein called HER2. HER2+ cancer cells grow and spread faster than HER2-negative cancer cells. When 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. When this happens, these words are used to describe it:

- **Locally advanced** means that cancer has grown to nearby tissue or lymph nodes, but has not yet spread to other parts of your body.
- **Unresectable** means that the cancer can't be removed with surgery.
- **Metastatic** means the cancer has spread from where it started to other parts of your body.

This clinical trial is for people with HER2+ locally advanced unresectable or metastatic breast cancer.

What are my treatment options?

If you have HER2+ locally advanced unresectable 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:

- **Targeted therapy** – treatment that works on specific cells to stop them from growing
- **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.
- **Hormone blocking therapy** – also called endocrine therapy. These are medicines that block or lower the level of hormones that cause certain breast cancers to grow.
- **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 locally advanced unresectable or metastatic breast cancer, but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove all or part of the cancer
- **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 an investigational drug, patritumab deruxtecan (also called MK-1022 or HER3-DXd), given in combination with anti-cancer drugs used as standard treatments, is safe to use for people with locally advanced unresectable or metastatic breast cancer (mBC). The other anti-cancer drugs that will be used in this trial are trastuzumab, pertuzumab, and tucatinib.

Patritumab deruxtecan is experimental. It has not been approved to be given alone, or in combination with other anti-cancer drugs, to treat any type of cancer.

Researchers will first test the investigational drug, patritumab deruxtecan, with trastuzumab to determine what dose to use of patritumab deruxtecan in the rest of the study. Researchers will then compare patritumab deruxtecan with pertuzumab and trastuzumab to patritumab deruxtecan with tucatinib and trastuzumab. Tucatinib, pertuzumab, and trastuzumab are targeted therapies for HER2+ breast cancer. They block the HER2 protein to help stop the growth and spread of cancer cells. These medications are commonly used in combination with other treatments, such as chemotherapy, to treat HER2+ breast cancer.

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:

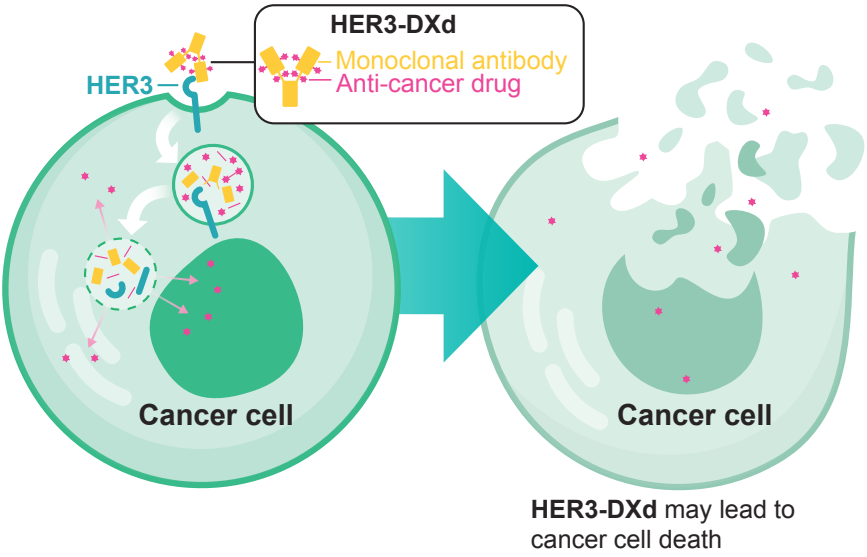
- **A monoclonal antibody:** A protein that binds to specific receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is HER3
- **An anti-cancer drug:** A type of drug that is meant to kill cancer cells
- **Linker:** Connects the anti-cancer drug to the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

How researchers think the investigational drug patritumab deruxtecan may work:

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.

Another way to think about patritumab deruxtecan



Who can join this trial?

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

For example, you must:

- Be at least 18 years old
- Have HER2+ breast cancer that is locally advanced or has spread to other areas of the body, and cannot be removed with surgery

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

You and your trial doctor will discuss:

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.

- 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
- How well you tolerate the study treatments

You may be in this study for up to 3 years.

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 treatments
- Blood and urine including pregnancy tests
- Physical exams
- Biomarker and genetic tests, which look for specific proteins or genes
- Eye exams
- Imaging scans such as CT scans or MRIs, which are scans that help the doctor see the cancer inside your body
- Brain scans
- Bone scans
- Electrocardiograms (ECG), Echocardiograms (ECHO), and MUGA scans, which are tests that look for signs of heart problems

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.

What treatments will I get?

The treatments you get will depend what previous treatments you have received for your metastatic breast cancer.

- **Group 1** will get the investigational combination of patritumab deruxtecan and trastuzumab
- **Group 2** will get the investigational combination of patritumab deruxtecan and trastuzumab with pertuzumab
- **Group 3** will get the investigational combination of patritumab deruxtecan and trastuzumab with tucatinib

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

Thank you for learning about HER2-positive locally advanced unresectable or 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
- Contact Merck by
  - Visiting **www.merckoncologyclinicaltrials.com**
  - Scanning this QR code:

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For more information, contact our research staff: