HER2CLIMB-05

HER2+ METASTATIC BREAST CANCER

Help to make an impact on the future: Contribute to important HER2-positive breast cancer treatment research

Information about the HER2CLIMB-05 Clinical Research Study investigating the potential to maximize the benefits of HER2-positive breast cancer treatment

www.her2climb05.com

ClinicalTrials.gov Identifier: NCT05132582
EudraCT Number: 2021-002491-39

This brochure is intended to be shared with people who may be able to take part in the HER2CLIMB-05 Clinical Research Study.

About HER2-positive breast cancer

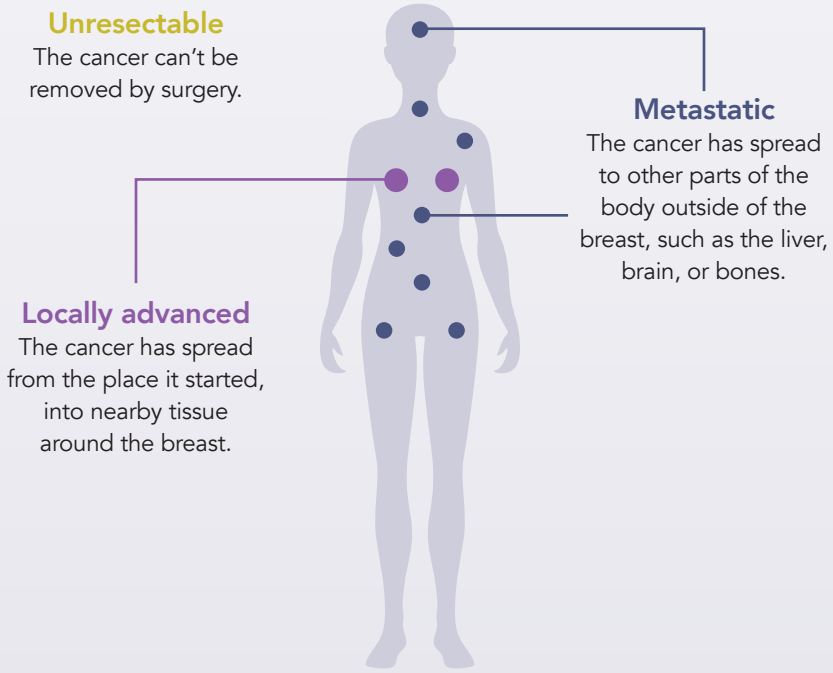
What is HER2-positive breast cancer?

HER2 is a protein that is found in our cells, including our breast cells. A normal amount of HER2 is healthy — it helps to control how a cell grows, divides, and repairs itself. However, having high levels of HER2 can cause cells to grow out of control, which can lead to cancer.

If you have HER2-positive breast cancer, it means that your cancer cells have higher than normal levels of the HER2 protein. HER2-positive breast cancers tend to grow and spread faster than other breast cancers and can occur in both men and women.

What is "locally advanced" or "metastatic" HER2-positive breast cancer?

The HER2CLIMB-05 Clinical Research Study is exploring an investigational study drug for people living with **unresectable locally advanced** or **metastatic** HER2-positive breast cancer.



About the HER2CLIMB-05 Clinical Research Study

The HER2CLIMB-05 Clinical Research Study is looking to explore how well an investigational study drug works as a maintenance therapy for metastatic HER2-positive breast cancer.

> *Maintenance therapy is a type of ongoing treatment that is given to help stop the cancer from coming back or getting worse, after the first treatment has been given.*

Previous research has shown positive results in the use of the investigational study drug for those living with metastatic HER2-positive breast cancer. This clinical research study will aim to find out whether the investigational study drug will improve current standard of care and improve the quality of life for those living with HER2-positive breast cancer.

> *People living with metastatic HER2-positive breast cancer are at a higher risk of developing cancer in the brain. If you have cancer in your brain, you may still be able to take part in this clinical research study.*

Who can take part?

You may be able to take part in the clinical research study if you:

- Are aged 18 years old or older
- Have HER2-positive breast cancer that has grown, spread to other parts of the body (is metastatic), or can't be removed by surgery
- Have received treatment or are about to start your first treatment with trastuzumab, pertuzumab and chemotherapy for HER2-positive breast cancer
- Have no signs of cancer in your brain, or have cancer in your brain that is stable and not showing any symptoms

Please note that this is not a complete list of criteria; you will need to answer some additional health-related questions and take part in some medical tests to confirm that you can join the clinical research study.

About the investigational study drug

What drug is being investigated in this clinical research study?

Tucatinib

Tucatinib has been approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Swissmedic, Health Canada, and the Therapeutic Goods Administration (TGA) in Australia for those living with HER2-positive breast cancer that has grown, spread to other parts of the body, or can't be removed by surgery.

Alongside receiving the investigational study drug (tucatinib) or placebo, everyone who takes part in this clinical research study will have already received their first treatment with trastuzumab and pertuzumab, or the combination treatment Phesgo™, which are approved drugs that are often used to treat HER2-positive breast cancer.

What does "investigational" mean?

Tucatinib is investigational in this clinical research study because it has not yet been approved for use in combination with trastuzumab and pertuzumab and as a first-line maintenance therapy. This clinical research study will help us to prove how well tucatinib plus trastuzumab and pertuzumab works as a maintenance therapy, compared with trastuzumab and pertuzumab alone.

How is the investigational study drug given?

The study drugs are given in 21-day cycles (every 21 days). The number of cycles will vary depending on your response to the study drug.

Tucatinib or the placebo will be taken by swallowing oval- or round-shaped tablets, twice a day, every day. You will receive a "dosing guide," which provides more information about the tablets, such as when and how to take them.

Trastuzumab and pertuzumab are given on day 1 of the 21-day cycle, and may be given to you:

- As an infusion into a vein in your arm (known as intravenous, or IV)
- As an injection under your skin
- As an IV and an injection under your skin

Taking part in the clinical research study

What happens before I take part?

To take part in the HER2CLIMB-05 Clinical Research Study, you will have already received your first treatment with trastuzumab and pertuzumab from your care team.

Upon entering the clinical research study, you will continue to receive trastuzumab and pertuzumab, and either the investigational study drug or placebo.

What happens during the clinical research study?

If you choose to join the clinical research study, you'll first have some tests to see if you are able to take part. This is called the "screening period."

If you can and choose to take part, you'll be randomly assigned (like flipping a coin) to receive the investigational study drug or a placebo, alongside trastuzumab and pertuzumab.

A placebo looks exactly like the investigational study drug, but it doesn't contain any active medicine.

Placebos are an important part of clinical research studies as they provide researchers with a comparison against the investigational study drug. This is how research can prove the investigational study drug is safe.

Please note: If you are assigned to receive the placebo, you will still receive your current standard of care.

Why is this clinical research study important?

This clinical research study is important to find out whether the investigational study drug will extend the treatment benefits of the current standard of care for those living with HER2-positive breast cancer.

Throughout the clinical research study, assessments and procedures will take place to find out how well the investigational study drug works at helping to stop the cancer from getting worse, and if it improves the quality of life for those taking part. These may include:

- Questions about yourself, your health, and your day-to-day activities
- A physical exam
- Blood samples
- Brain and body scans
- A pregnancy test (if you are able to get pregnant)
- A sample of your tumor

How much of my time will be needed?

How long you take part in the clinical research study depends on how you respond to the treatment. If your cancer is stable or gets better, you may keep getting the study drugs until the study closes. Your study doctor will give you further advice throughout the clinical research study.

You can stop taking part in the clinical research study at any time by simply telling your study doctor. This won't affect your regular medical care.

The study doctor will review all known potential side effects with you so that you are fully informed and can ask any questions that you may have about participating in the study.

The clinical research study appointment schedule

This table shows which days you need to visit the clinic, what happens during those visits, and how much of your time will be needed at each visit.

You will take the investigational study drug or placebo as a tablet twice each day.

Other assessments may take place outside of this schedule, such as brain or body scans every 9 or 27 weeks. Your study doctor will give you more information about this before you take part.

1 Every cycle 2–6 hours	2	3	4	5	6	7
8	9	10	11	12 Cycle 1 and 2 only 1–2 hours	13	14
15	16	17	18	19	20	21

Physical exam · Blood samples · Questionnaires · Administration of the study drugs

Other important information you should know

Before joining the clinical research study, you will be given an informed consent form (ICF), which will explain in further detail the information included in this guide. You will always be able to speak to your treating physician if you have any questions or concerns.

Will being in this research benefit you?

It is not known if taking part in this clinical research study will help you — your health may or may not get better. However, the information from this study will help doctors learn more about the study drugs, which could help those living with HER2-positive breast cancer in the future.

Are there any risks to taking part in this clinical research study?

The investigational study drug may cause side effects. A side effect is anything a drug does to your body that is not part of how the drug treats disease. Before you join the clinical research study, the study doctor will explain the potential side effects, and you will be closely monitored for any side effects throughout the clinical research study.

What happens to the information collected in this research?

Your information will be used for research purposes only. Any information shared outside of the study will not contain any personal information that could be used to identify you (like your name or address).

Are there any costs involved with this clinical research study?

Direct costs for those who take part will be limited. The sponsor of this clinical research study, Seagen, may pay for some of the costs involved in this study. More information about the costs involved is provided in the ICF or Travel Reimbursement Agreement.

Notes

If you have any questions, take note of them here, and please do not hesitate to ask a member of the study team.

Study team contact information:

Name:

Telephone:

Email:

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