



MK-5684-015

Learn about a clinical trial for **HR+ /HER2- Unresectable Locally Advanced or Metastatic Breast Cancer**

In this brochure, you will learn about **metastatic or unresectable locally advanced HR+ /HER2- breast cancer** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational drug, MK-5684, can help stop or slow the growth of cancer in people with unresectable locally advanced or metastatic HR+ /HER2- breast cancer. You can use this brochure to talk with your doctor about this trial.



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What is 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 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.

Doctors can use the HR and HER2 proteins to identify and treat your cancer.

What does metastatic or unresectable locally advanced mean?

Metastatic means that the cancer has spread to other parts of the body. **Unresectable locally advanced** means the cancer:

- Has come back or gotten worse
- Can't be treated with surgery
- Has not spread to other parts of the body

What are my treatment options?

If you have HR+/HER2- 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
- **Hormone therapy** - medicines that block or lower the level of hormones that cause certain cancers to grow
- **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 HR+/HER2- unresectable locally advanced or metastatic breast cancer but it helps keep you as comfortable as possible.
- **Surgery** - treatment to remove all or part of the cancer
- **Watchful waiting** - your care team might wait and watch the cancer before they use any treatment (also called active surveillance)
- **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 drug, MK-5684, is safe and if it can help stop or slow the growth of cancer cells in people with unresectable locally advanced or metastatic HR+ | HER2- breast cancer.

Researchers do not yet know if MK-5684 will work to treat unresectable locally advanced or metastatic HR+/HER2- breast cancer.

Researchers will compare MK-5684 to a hormone therapy of the trial doctor's choice. This is the usual treatment for people with this type of cancer.

What is the treatment being studied?

This clinical trial is studying the investigational drug MK-5684 (also called opevesostat), to see if it may slow or stop the growth of HR+|HER2- breast cancer by stopping the body from making steroid hormones.

About MK-5684 (opevesostat)

Steroid hormones are chemical messengers that help your body control processes, such as:

- Your metabolism – the process that turns your food and drinks into energy in your body
- Your immune system – the process that protects your body from infection
- Blood pressure
- Development of sexual characteristics such as puberty

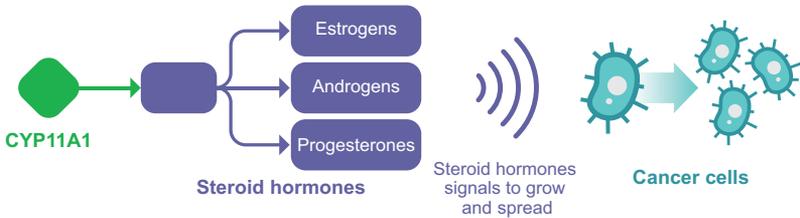
Estrogens, progesterones, and androgens are types of steroid hormones that certain cancer cells can use to grow and spread.

Many proteins in the body help make estrogens, progesterones, and androgens. One of these proteins is called CYP11A1.

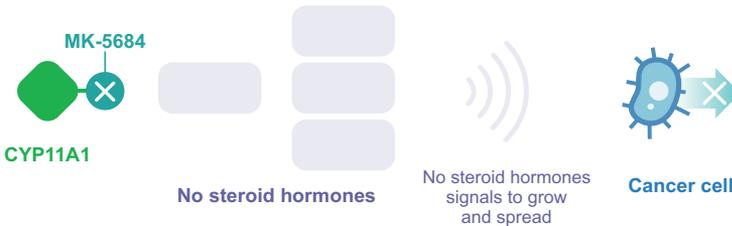
MK-5684 may help slow or stop cancer cell growth by blocking CYP11A1 from making these and other steroid hormones.

Another way to think about MK-5684 (opevesostat)

The body uses **CYP11A1** to make many different **steroid hormones**. Certain **cancer cells** can use steroid hormones, such as estrogens, Progesterones, and androgens, to **grow and spread**.



This clinical trial looks at whether the blockage of **CYP11A1** from making **steroid hormones**, caused by **MK-5684**, will stop **cancer cells** from growing and spreading.



What is Supportive Adrenal Therapy (SAT) and adrenal crisis?

Your body needs steroid hormones to function. Since the investigational drug, MK-5684, prevents the body from making any steroid hormones, participants in this trial will need to also take **supportive adrenal therapy (SAT)** every day. SAT drugs act as a replacement for some of the steroid hormones. People who take MK-5684 in this trial must also take 2 SAT drugs called fludrocortisone and dexamethasone.

It is very important to take SAT drugs with MK-5684. Taking MK-5684 without any SAT drugs can cause **adrenal crisis**, a serious medical emergency that can result in death.

What is adrenal crisis?

Adrenal crisis is when your body has a very low level of the steroid hormones that are usually made by your adrenal glands. Your adrenal glands make these hormones and are located at the top of your kidneys.

Signs and symptoms of adrenal crisis include:

- Severe tiredness, weakness, lack of energy
- Craving salt
- Low blood pressure, feeling lightheaded or dizziness when standing up
- Abdominal pain, tenderness
- Nausea (feeling sick to your stomach) or vomiting (throwing up)
- Fever
- Confusion or increased sleepiness
- Back and/or leg cramps or spasms
- Rapid breathing
- Unusual and excessive sweating

Adrenal crisis is a serious medical emergency. If you have any of these symptoms while in this trial, seek medical care right away. It can be treated with a steroid drug called hydrocortisone.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must:

- Be 18 years of age or older
- Not be pregnant
- Have HR+/HER2- metastatic or advanced breast cancer that:
 - Has spread from the original site
 - Cannot be removed through surgery,
 - Has gotten worse after at least 1 prior treatment

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



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.

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 treatments
- Blood and urine tests
- Physical exams
- Imaging scans such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)

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 on which group you are randomly placed in. This trial has two groups:

- **Group 1** will receive MK-5684 and supportive adrenal therapy (SAT)
- **Group 2** will receive hormone therapy of the trial doctor's choice

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

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



Thank you for learning about HR+ /HER2- metastatic or unresectable locally advanced breast cancer and this clinical trial

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

Your questions and notes:

You can use this space to write down notes or questions about this trial.

To learn more

To learn more about this trial, you can

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

