» Go to Healthcare Professionals



help?

This information is for Patients & Caregivers

How can KADCYLA help? What can I expect while on KADCYLA?

Are there financial

How can KADCYLA

What other types of

Safety First!

Before you start exploring, please read side effect information. **» View now** 

## KADCYLA may help you live longer

### Is KADCYLA right for you?

KADCYLA is for the treatment of HER2-positive metastatic breast cancer. Because you have this type of breast cancer, KADCYLA may be an option for you.

# Women with HER2-positive metastatic breast cancer can take KADCYLA

Because everyone is different, no one can say for sure if KADCYLA will work for you, or for how long it will keep working.

KADCYLA has been studied only in women with HER2-positive metastatic breast cancer. These women had already received Herceptin<sup>®</sup> (trastuzumab) and a taxane (chemotherapy)



In the study, women took either KADCYLA or a combination of Tykerb® (lapatinib) and Xeloda® (capecitabine)

### KADCYLA helped women live longer

Women taking KADCYLA lived longer, on average, than

rb and Xeloda

KADCYLA Patient Support Line

4HER Patient Support App

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KADCYLA increased the chance of stopping the growth and spread of cancer by 35% over Tykerb and Xeloda

## Hair loss was not common in either study group

Less than 5% of women who took KADCYLA or Tykerb and Xeloda lost their hair (3.5% and 4.5%, respectively)

# What are the most common side effects of KADCYLA?

The most common side effects seen in people taking KADCYLA were:

Tiredness Nausea Pain that affects the bones, muscles, ligaments, and tendons Bleeding Low platelet count Headache Liver problems Constipation Nosebleeds

Tykerb is a registered trademark of GlaxoSmithKline.

Next: See how KADCYLA is given



### Who is KADCYLA for?

KADCYLA<sup>®</sup> (1) is approved to treat HER2-positive breast cancer that has spread to other parts of the body (metastatic breast cancer) after prior treatment with trastuzumab (Herceptin) and a taxane. Prior treatment could have been for the initial treatment of breast cancer or for the treatment of cancer that had spread to other parts of the body.

### Important Safety Information

## What is the most important safety information I should know about KADCYLA?

KADCYLA is not the same medicine as trastuzumab (Herceptin).

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Is it Right for your Cancer | KADCYLA® (ado-trastuzumab emtansine)

Symptoms of liver problems may include vomiting, nausea, eating disorder (anorexia), yellowing of the skin (jaundice), stomach pain, dark urine, or itching

#### **Heart problems**

KADCYLA may cause heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure). Symptoms may include swelling of the ankles or legs, shortness of breath, cough, rapid weight gain of greater than 5 lbs in less than 24 hours, dizziness or loss of consciousness, or irregular heartbeat

#### Pregnancy

Receiving KADCYLA during pregnancy can result in the death of an unborn baby and birth defects. Birth control should be used while you receive KADCYLA and for 6 months after your last dose of KADCYLA

If you are exposed to KADCYLA during pregnancy, contact your healthcare provider right away; you are also encouraged to enroll in the **MotHER Pregnancy Registry** by calling 1-800-690-6720

If you are a mother who is breastfeeding, you should talk with your doctor about either stopping breastfeeding or stopping KADCYLA

Contact your doctor right away if you experience symptoms associated with these side effects.

## What are the additional possible serious side effects of KADCYLA?

Not all people have serious side effects; however, side effects with KADCYLA treatment are common. It is important to know what side effects may happen and what symptoms you should watch for.

#### Lung problems

KADCYLA may cause lung problems, including inflammation of the lung tissue, which can be life-threatening. Signs of lung problems may include trouble breathing, cough, tiredness, and fluid in the lungs

#### Infusion-related reactions

Symptoms of an infusion-related reaction may include one or more of the following: the skin getting hot or red (flushing), chills, fever, trouble breathing, low blood pressure, wheezing, tightening of the muscles in the chest around the airways, or a fast heartbeat. Your doctor will monitor you for infusion-related reactions

#### **Serious Bleeding**

KADCYLA can cause life-threatening bleeding. Taking KADCYLA with other medications used to thin your blood (antiplatelet) or prevent blood clots (anticoagulation) can increase your risk of bleeding. Your doctor should provide additional monitoring if you are taking one of these other drugs

KADCYLA even when blood thinners are not also being taken

#### Low platelet count

Low platelet count may happen during treatment with KADCYLA. Platelets help your blood to clot. Signs of low platelets may include easy bruising, bleeding, and prolonged bleeding from cuts. In mild cases there may not be any symptoms

#### Nerve damage

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Symptoms may include numbness and tingling, burning or sharp pain, sensitivity to touch, lack of coordination, muscle weakness, or loss of muscle function

#### Skin reactions around the infusion site

KADCYLA may leak from the vein or needle and cause reactions such as redness, tenderness, skin irritation, or pain or swelling at the infusion site. If this happens, it is more likely to happen within 24 hours of the infusion

### How will my doctor know if KADCYLA is right for me?

You must have a HER2 test to determine if your cancer is HER2-positive before taking KADCYLA, because benefit has been shown only in patients whose tumors are HER2-positive.

### What are the most common side effects of KADCYLA?

The most common severe side effects of KADCYLA are:

Low platelet count Liver problems Low levels of red blood cells Nerve problems Low levels of potassium in the blood Tiredness The most common side effects seen in people taking KADCYLA were: Tiredness Nausea Pain that affects the bones, muscles, ligaments, and tendons Bleeding Low platelet count Headache Liver problems Constipation **Nosebleeds** 

You are encouraged to report side effects to Genentech and the FDA. You may

Find authenticated court documents without watermarks at docketalarm.com.

www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see KADCYLA full Prescribing Information, including Most Important Safety Information, for additional Important Safety Information.

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