

NOW APPROVED

 **ENHERTU**<sup>®</sup>  
fam-trastuzumab deruxtecan-nxki  
20 mg/mL INJECTION FOR INTRAVENOUS USE

## A New Treatment Option for People Previously Treated for HER2+ Unresectable or Metastatic Breast Cancer

Visit **ENHERTU.com** for more information.



### What is ENHERTU?

ENHERTU is a prescription medicine used in adults to treat human epidermal growth factor receptor 2 (HER2)-positive breast cancer that cannot be removed by surgery or that has spread to other parts of your body (metastatic), and who have received two or more prior anti-HER2 breast cancer treatments.

ENHERTU was FDA approved for this use based on a clinical study that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results.

It is not known if ENHERTU is safe and effective in children.

### Important Safety Information

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

**ENHERTU can cause serious side effects, including:**

**Lung problems that may be severe, life-threatening or that may lead to death.** If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- Cough
- Trouble breathing or shortness of breath
- Fever
- Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

Please see Important Safety Information throughout as well as on pages 11 to 14, and [click here for full Prescribing Information](#), including **Boxed WARNING**, and [click here for Medication Guide](#).



## What is ENHERTU?

ENHERTU (fam-trastuzumab deruxtecan-nxki) is a prescription medicine used to treat adult patients with **H**uman **E**pidermal growth factor **R**eceptor **2** (HER2)-positive breast cancer that:

- Cannot be removed by surgery or that has spread to other parts of your body (known as metastatic), **and**
- Have received two or more prior anti-HER2 breast cancer treatments

ENHERTU was FDA approved for this use based on a clinical study that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results. It is not known if ENHERTU is safe and effective in children.

**Ask your healthcare provider if ENHERTU is right for you.**

### Select Important Safety Information (cont'd)

**Low white blood cell count (neutropenia).** Low white blood cell counts are common with ENHERTU and can sometimes be severe. Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose. Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU.

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# How does ENHERTU work?

ENHERTU is made up of two cancer-fighting agents: an antibody attached to chemotherapy.<sup>1,2</sup>

- ENHERTU works by attacking HER2+ cancer cells and delivering chemotherapy to them
- Although ENHERTU is designed to target HER2+ cancer cells it may still affect some healthy cells

# How was ENHERTU studied?

ENHERTU was studied in 184 females with HER2+ unresectable and/or metastatic breast cancer who had previously been treated with two or more prior anti-HER2 therapies.

- Half of the patients in this study received 5 or more drugs for advanced or metastatic breast cancer

## Select Important Safety Information (cont'd)

**Heart problems that may affect your heart's ability to pump blood.** Your healthcare provider will check your heart function before starting treatment with ENHERTU. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- New or worsening shortness of breath
- Irregular heartbeat
- Coughing
- Sudden weight gain
- Feeling tired
- Dizziness or feeling light-headed
- Swelling of your ankles or legs
- Loss of consciousness

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## ENHERTU helped shrink tumors in over half of the patients in the clinical study

Six out of ten patients (60.3%) had a response to ENHERTU treatment, meaning the tumor shrank in size by at least 30%. This is called an objective response rate (or ORR).

- Some people (4.3% or about 4 in 100 people) achieved what is called a complete response (or CR), which means that the tumor shrank to the point where the healthcare provider was no longer able to detect it through tests known as imaging
- The majority of people (56%) taking ENHERTU achieved some tumor shrinkage called a partial response (or PR)



**6 out of 10**  
patients responded  
to ENHERTU treatment

### Select Important Safety Information (cont'd)

**Your healthcare provider will check you for these side effects during your treatment with ENHERTU. Your healthcare provider may reduce your dose, delay treatment or completely stop treatment with ENHERTU if you have severe side effects.**

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# ENHERTU kept working for nearly 15 months

111 of the 184 people in the clinical study receiving ENHERTU responded to treatment. The length of time that they maintained their response to ENHERTU is called the duration of response (DOR).

While the length of time varied, ENHERTU kept working for a median of 14.8 months for patients who responded to treatment.<sup>a</sup>

<sup>a</sup>Median is the middle number in a group of numbers arranged from lowest to highest.



## Select Important Safety Information (cont'd)

**Harm to your unborn baby.** Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ENHERTU.

- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ENHERTU.
- **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 7 months after the last dose.
- **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 4 months after the last dose.

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# What is the most important information you should know about ENHERTU?

**ENHERTU can cause serious side effects, including:**

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## **Lung problems, like interstitial lung disease, that may be severe, life-threatening or that may lead to death**

- Call or see your healthcare provider right away if you develop any of the following signs and symptoms or if these symptoms get worse:
  - Cough
  - Trouble breathing or shortness of breath
  - Fever
  - Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

If you develop lung problems your healthcare provider may treat you with corticosteroid medicines.



## **Low white blood cell count (neutropenia)**

- Low white blood cell counts are common with ENHERTU and can sometimes be severe
- Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose
- Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU

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# What is the most important information you should know about ENHERTU? (cont'd)

**ENHERTU can cause serious side effects, including:**



## **Heart problems that may affect your heart's ability to pump blood**

- Your healthcare provider will check your heart function before starting treatment with ENHERTU

### **Signs and symptoms may include:**

- New or worsening shortness of breath
- Coughing
- Feeling tired
- Swelling of your ankles or legs
- Irregular heartbeat
- Sudden weight gain
- Dizziness or feeling light-headed
- Loss of consciousness

**Your healthcare provider will check you for these side effects during your treatment with ENHERTU. Your healthcare provider may reduce your dose, delay treatment or completely stop treatment with ENHERTU if you have severe side effects.**

Getting medical treatment right away may help keep these problems from becoming more serious.

**Call or see your healthcare provider right away if you develop any symptoms of the above problems or if these symptoms get worse.**

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# What are the possible side effects of ENHERTU?

**ENHERTU can cause serious side effects. See pages 6-7 and 11-14 for more information.**

## **The most common side effects of ENHERTU include:**

- Nausea
- Feeling tired
- Vomiting
- Hair loss
- Constipation
- Decreased appetite
- Low red blood cell counts
- Low white blood cell counts
- Diarrhea
- Cough
- Low platelet counts

ENHERTU may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of ENHERTU. Tell your healthcare provider if you experience any side effects, including those not listed in this brochure.

### **Call your healthcare provider for medical advice about side effects.**

You are encouraged to report negative side effects of ENHERTU by calling **1-877-437-7763**.

If you prefer to report these to the FDA, visit **[www.FDA.gov/medwatch](http://www.FDA.gov/medwatch)** or call **1-800-FDA-1088 (1-800-332-1088)**.

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## How will I receive ENHERTU?

ENHERTU is given once every 3 weeks by intravenous (IV) infusion by your healthcare provider.



### Your healthcare provider will decide how many treatments you need

- Your healthcare provider may slow down or temporarily stop your infusion of ENHERTU if you have an infusion-related reaction, or permanently stop ENHERTU if you have severe infusion reactions
- If you miss a planned dose of ENHERTU, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle

## How long do the infusions take?

**Your first infusion**  
takes about 90 minutes



IF WELL  
TOLERATED

**After the first infusion,**  
infusions take about 30 minutes



**Your healthcare provider may interrupt your dose of ENHERTU if you experience side effects.**

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## After your healthcare provider prescribes ENHERTU, ENHERTU4U can help you with access and financial assistance



### Access

ENHERTU4U is here to help your healthcare provider verify your insurance coverage and get you access to treatment with ENHERTU.



### Financial Assistance

We have multiple options to help you afford your treatment. Your healthcare provider can provide more information about how ENHERTU4U can help.



### Talk to an ENHERTU nurse

ENHERTU4U has nurses available to speak to you and answer questions about your treatment. You may call 1-833-ENHERTU (1-833-364-3788) to speak to a nurse.

For support from ENHERTU4U, please call 1-833-ENHERTU (1-833-364-3788) or visit [www.ENHERTU4U.com](http://www.ENHERTU4U.com).

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# Important Safety Information

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

**ENHERTU can cause serious side effects, including:**

**Lung problems that may be severe, life-threatening or that may lead to death.** If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- Cough
- Trouble breathing or shortness of breath
- Fever
- Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

### **Low white blood cell count (neutropenia).**

Low white blood cell counts are common with ENHERTU and can sometimes be severe. Your healthcare provider will check your white

blood cell counts before starting ENHERTU and before starting each dose. Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU.

### **Heart problems that may affect your heart's ability to pump blood.**

Your healthcare provider will check your heart function before starting treatment with ENHERTU. Tell your healthcare provider right away if you get any of the following signs and symptoms:

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## Important Safety Information (cont'd)

**Your healthcare provider will check you for these side effects during your treatment with ENHERTU. Your healthcare provider may reduce your dose, delay treatment or completely stop treatment with ENHERTU if you have severe side effects.**

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- **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 7 months after the last dose.
- **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 4 months after the last dose.

**Before you receive ENHERTU, tell your healthcare provider about all of your medical conditions, including if you:**

- Have lung or breathing problems.
- Have signs or symptoms of an infection.
- Have or have had any heart problems.
- Are breastfeeding or plan to breastfeed. It is not known if ENHERTU passes into your breast milk. Do not breastfeed during treatment with ENHERTU and for 7 months after the last dose.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### **How will I receive ENHERTU?**

- You will receive ENHERTU into your vein through an intravenous (IV) line by your healthcare provider.
- ENHERTU is given 1 time every three weeks (21-day treatment cycle).
- Your healthcare provider will decide how many treatments you need.

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### **What are the possible side effects of ENHERTU?**

**ENHERTU can cause serious side effects. See “What is the most important information I should know about ENHERTU?”**

### **The most common side effects of ENHERTU include:**

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## Important Safety Information (cont'd)

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### **What is ENHERTU?**

ENHERTU is a prescription medicine used in adults to treat human epidermal growth factor receptor 2 (HER2) positive breast cancer that cannot be removed by surgery or that has spread to other parts of your body (metastatic), and who have received two or more prior anti-HER2 breast cancer treatments.

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Find out more about ENHERTU  
by speaking with your  
healthcare provider

Go to **ENHERTU.com** for more information.

**References:** **1.** Ogitani Y, Aida T, Hagihara K, et al. DS-8201a, a novel HER2-targeting ADC with a novel DNA topoisomerase I inhibitor, demonstrates a promising antitumor efficacy with differentiation from T-DM1. *Clin Cancer Res.* 2016;22(20):5097-5108. **2.** Nakada T, Sugihara K, Jikoh T, Abe Y, Agatsuma T. The latest research and development into the antibody-drug conjugate, [fam-] trastuzumab deruxtecan (DS-8201a), for HER2 cancer therapy. *Chem Pharm Bull.* 2019;67(3):173-185.

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