

# A Guide to ENHERTU

A treatment option for previously treated adults with **HER2-positive (IHC 3+)** metastatic\* solid tumors who have no other treatment options

ENHERTU was FDA approved for this use based on clinical studies that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

\*Metastatic is defined as cancer that has spread to other parts of the body. HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry.

Not an actual patient.

## What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

- ENHERTU was FDA approved for this use based on clinical studies 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 (such as chest tightness, wheezing)

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# Your guide to ENHERTU

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Whether you have already started on or are considering treatment with ENHERTU, this brochure is designed to provide you with:

- Information about HER2 positivity and ENHERTU
- Clinical trial results
- Possible side effects, including serious ones
- Details about how you will receive ENHERTU
- Financial support options

It may be helpful for you to review this brochure with your healthcare team who can answer any further questions you may have.

## 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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## Understanding HER2 positivity

### What should I know about HER2 and HER2 positivity?

HER2 is a protein that tells cells to grow. When cells produce too much HER2, they can become cancerous.



Excessive amounts of HER2 can be found in many different tumors.



HER2 levels can be determined by a testing method called immunohistochemistry (IHC).



IHC 0 IHC 1+ IHC 2+ IHC 3+

HER2 IHC scores range from IHC 0 to IHC 3+.

ENHERTU is approved to treat certain adults who have HER2-positive (IHC 3+) metastatic solid tumors with a HER2 IHC score of 3+ and who progressed after previous treatment. Your IHC score helps your healthcare provider determine if you may be eligible for ENHERTU.

#### IMPORTANT SAFETY INFORMATION (cont'd)

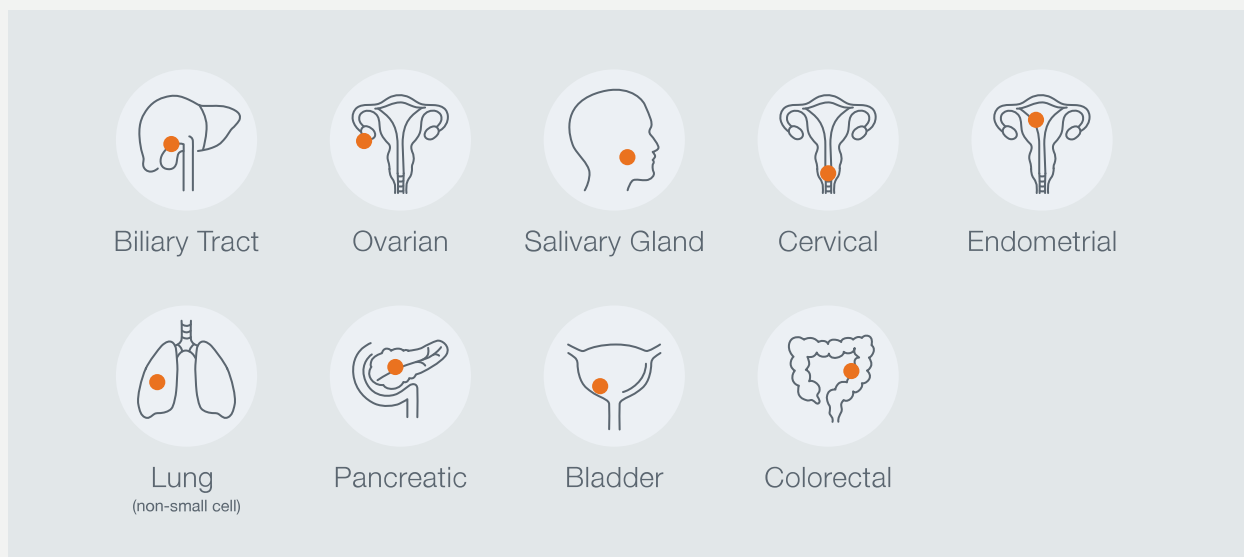
- **Heart problems that may affect your heart's ability to pump blood.** Your healthcare provider will check your heart function before starting treatment with ENHERTU. Tell your healthcare provider right away if you get any of the following signs and symptoms: • New or worsening shortness of breath • Coughing • Feeling tired • Swelling of your ankles or legs • Irregular heartbeat • Sudden weight gain • Dizziness or feeling light-headed • Loss of consciousness

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## Understanding HER2 positivity (cont'd)

The highest level of **HER2 positivity (IHC 3+)** occurs in many different types of solid tumors,\* including:



The highest level of HER2 positivity (IHC 3+) also occurs in multiple other tumor types.

\*A solid tumor is a mass of cancer cells that grows in organs, muscles, or bones.

### 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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## Clinical trials

**ENHERTU** was studied in 3 clinical trials of many different types of metastatic<sup>†</sup> solid tumors that had the **highest level of HER2 positivity (IHC 3+)**

**These 3 clinical trials included 192 previously treated adults:**

- **111 people** with various types of metastatic tumors, including biliary tract, pancreatic, ovarian, cervical, endometrial, bladder, salivary gland, and other cancers
- **17 people** with metastatic non-small cell lung cancer (mNSCLC)
- **64 people** with metastatic colorectal cancer (mCRC)

These studies only evaluated ENHERTU. There were no comparisons of results to other treatment options. Individual results may vary. ENHERTU may not work for everyone.

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

<sup>†</sup>Metastatic is defined as cancer that has spread to other parts of the body.

### 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 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 4 months after the last dose.

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## Overview of results

In the 3 clinical trials, about **half of people treated with ENHERTU had their tumors shrink\***

\*This is called the overall response rate.



A median is the middle number in a set of numbers.  
+ indicates that the response to treatment is ongoing.

<sup>†</sup>**Complete response** means there are no signs of cancer on a follow-up scan.

<sup>†</sup>**Partial response** means the tumors shrank by at least 30%.

<sup>§</sup>**Median duration of response** is the length of time half of the people who responded to ENHERTU continued to respond after the first response was seen.

mCRC, metastatic colorectal cancer; mNSCLC, metastatic non-small cell lung cancer.

## IMPORTANT SAFETY INFORMATION (cont'd)

**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.

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## Lung cancer results

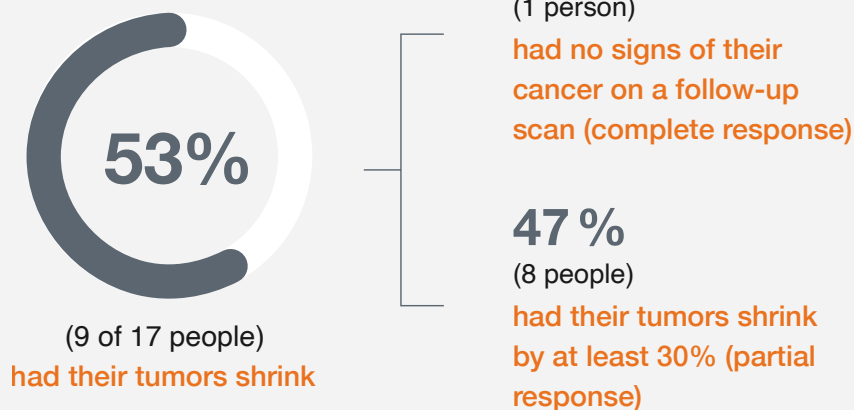


### Results with **ENHERTU** in adults with **metastatic non-small cell lung cancer**

These pages are limited to ENHERTU data in previously treated patients with lung cancer that is HER2 positive (IHC 3+) only; these data do not address all lung cancer clinical trial data for ENHERTU.

In the clinical trial of 17 people with previously treated HER2+ (IHC 3+) metastatic non-small cell lung cancer (mNSCLC), about 50% of people treated with ENHERTU had their tumors shrink.

#### Overall response rate



This is called the overall response rate.

#### IMPORTANT SAFETY INFORMATION (cont'd)

**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.
- Your healthcare provider will give you medicines before your infusion to help prevent nausea and vomiting.
- 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.

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## Lung cancer results (cont'd)



### Results with **ENHERTU** in adults with **metastatic non-small cell lung cancer**

**50% of people** who responded to **ENHERTU** were responding after **6.9 (range 4.0 to 11.7+) months**

This is called median duration of response.\*

+ indicates that the response to treatment is ongoing.

\*A median is the middle number in a set of numbers. Median duration of response is the length of time half of the people who responded to ENHERTU continued to respond after the first response was seen.

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

## IMPORTANT SAFETY INFORMATION (cont'd)

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?”**

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## Gastrointestinal cancer results



### Results with **ENHERTU** in adults with **metastatic colorectal cancer**

In the clinical trial of 64 people with previously treated HER2+ (IHC 3+) metastatic colorectal cancer (mCRC), nearly 50% of people treated with ENHERTU had their tumors shrink.

#### Overall response rate



This is called the overall response rate.

#### IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of ENHERTU when used at the 5.4 mg/kg dose include:

- Low white blood cell counts
- Nausea
- Low red blood cell counts
- Feeling tired
- Low platelet counts
- Increased liver function tests
- Vomiting
- Hair loss
- Constipation
- Low levels of blood potassium
- Decreased appetite
- Diarrhea
- Muscle or bone pain

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## Gastrointestinal cancer results (cont'd)



### Results with **ENHERTU** in adults with **metastatic colorectal cancer**

**50% of people** who responded to **ENHERTU** were responding after **5.5 (range 1.3+ to 9.7+) months**

This is called median duration of response.\*

+ indicates that the response to treatment is ongoing.

\*A median is the middle number in a set of numbers. Median duration of response is the length of time half of the people who responded to ENHERTU continued to respond after the first response was seen.

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## IMPORTANT SAFETY INFORMATION (cont'd)

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.

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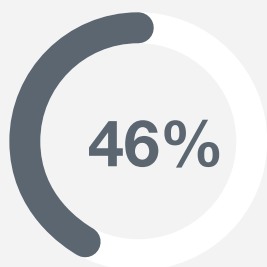
## Gastrointestinal cancer results (cont'd)



### Results with **ENHERTU** in people with **metastatic biliary tract cancer**

Outcomes in selected tumor types in the clinical trial of 111 people with various previously treated HER2+ (IHC 3+) metastatic cancers\*

Overall response rate



(10 of 22 people)

**had their tumors shrink**

#### **Duration of response (range)<sup>†</sup>**

People who responded to ENHERTU responded for a range of **2.1 to 22.0+ months**

+ indicates that the response to treatment is ongoing.

\*Tumor types included biliary tract (22 people), pancreatic (5 people), ovarian (15 people), cervical (10 people), endometrial (16 people), bladder (27 people), and other cancers (16 people).

<sup>†</sup>Duration of response is the length of time the people who responded to ENHERTU continued to respond after the first response was seen.

## IMPORTANT SAFETY INFORMATION (cont'd)

These are not all of the possible side effects of ENHERTU. Call your doctor for medical advice about side effects. You may report side effects to Daiichi Sankyo at 1-877-437-7763 or to FDA at 1-800-FDA-1088.

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## Gastrointestinal cancer results (cont'd)



### Results with **ENHERTU** in people with **metastatic pancreatic cancer**

#### Overall response rate

0 of 5 people with pancreatic cancer had their tumors shrink

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

## IMPORTANT SAFETY INFORMATION (cont'd)

### What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

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

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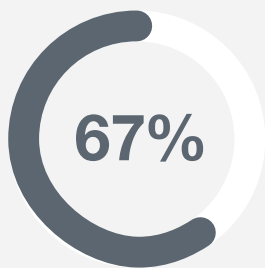
## Gynecologic cancer results

Outcomes in selected tumor types in the clinical trial of 111 people with various previously treated HER2+ (IHC 3+) metastatic cancers\*



### Results with **ENHERTU** in people with **ovarian cancer**

Overall response rate



(10 of 15 people)

had their tumors shrink

#### **Duration of response (range)<sup>†</sup>**

People who responded to ENHERTU responded for a range of **1.3 to 27.9+ months**

+ indicates that the response to treatment is ongoing.

## IMPORTANT SAFETY INFORMATION (cont'd)

**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 (such as chest tightness, wheezing)

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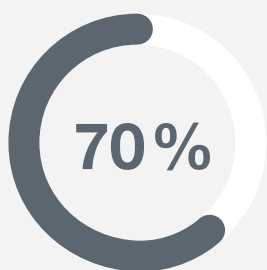


## Gynecologic cancer results (cont'd)



### Results with **ENHERTU** in people with **cervical cancer**

Overall response rate



(7 of 10 people)

had their tumors shrink

#### **Duration of response (range)<sup>†</sup>**

People who responded to ENHERTU responded for a range of **7.2+ to 25.0+ months**

+ indicates that the response to treatment is ongoing.

\*Tumor types included biliary tract (22 people), pancreatic (5 people), ovarian (15 people), cervical (10 people), endometrial (16 people), bladder (27 people), and other cancers (16 people).

<sup>†</sup>Duration of response is the length of time the people who responded to ENHERTU continued to respond after the first response was seen.

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## 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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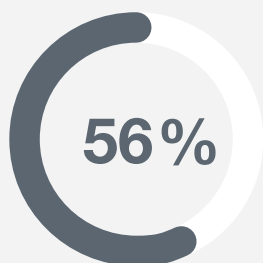
## Gynecologic cancer results (cont'd)

Outcomes in selected tumor types in the clinical trial of 111 people with various previously treated HER2+ (IHC 3+) metastatic cancers\*



### Results with **ENHERTU** in people with **endometrial cancer**

Overall response rate



(9 of 16 people)

had their tumors shrink

#### **Duration of response (range)<sup>†</sup>**

People who responded to ENHERTU responded for a range of **5.8 to 23.7+ months**

+ indicates that the response to treatment is ongoing.

## 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 • Coughing • Feeling tired • Swelling of your ankles or legs • Irregular heartbeat • Sudden weight gain • Dizziness or feeling light-headed • Loss of consciousness

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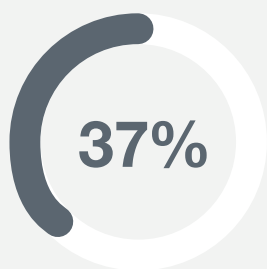
## Bladder cancer results

Outcomes in selected tumor types in the clinical trial of 111 people with various previously treated HER2+ (IHC 3+) metastatic cancers\*



### Results with **ENHERTU** in people with **bladder cancer**

Overall response rate



(10 of 27 people)

had their tumors shrink

#### Duration of response (range)<sup>†</sup>

People who responded to ENHERTU responded for a range of **2.8 to 19.7+ months**

+ indicates that the response to treatment is ongoing.

\*Tumor types included biliary tract (22 people), pancreatic (5 people), ovarian (15 people), cervical (10 people), endometrial (16 people), bladder (27 people), and other cancers (16 people).

<sup>†</sup>Duration of response is the length of time the people who responded to ENHERTU continued to respond after the first response was seen.


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

## 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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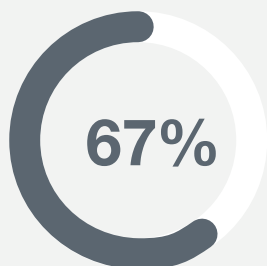
## Salivary gland cancer results

Outcomes in selected tumor types in the clinical trial of 111 people with various previously treated HER2+ (IHC 3+) metastatic cancers\*



### Results with **ENHERTU** in people with **salivary gland cancer†**

Overall response rate



(6 of 9 people)

had their tumors shrink

#### Duration of response (range)‡

People who responded to ENHERTU responded for a range of **5.6 to 20.1 months**

\*Tumor types included biliary tract (22 people), pancreatic (5 people), ovarian (15 people), cervical (10 people), endometrial (16 people), bladder (27 people), and other cancers (16 people).

†The tumors studied in the group of 16 people with other cancers included salivary gland (9 people); mouth and throat (oropharyngeal) (1 person); vulvar (1 person); skin cancer affecting the sweat glands (1 person); tear gland (1 person); lip/oral (1 person); esophageal (1 person); and esophageal (squamous cell) (1 person).

‡Duration of response is the length of time the people who responded to ENHERTU continued to respond after the first response was seen.

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#### 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 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 4 months after the last dose.

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

ENHERTU can cause serious side effects. Some serious or life-threatening side effects may affect your lungs, heart, or white blood cell count, affecting your ability to fight infection.

Pay special attention to new or worsening symptoms as they may be related to:



### **Lung problems 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 (such as chest tightness, wheezing)

If lung problems develop, 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 I should know about 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:

- 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.**



### 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 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 4 months after the last dose

**These are not all of the possible side effects of ENHERTU.  
Call your doctor for medical advice about side effects.**

Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS](#), and [click here for Medication Guide](#).

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20 mg/mL INJECTION FOR INTRAVENOUS USE



Not actual patients.

Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information](#), including **Boxed WARNINGS**, and [click here for Medication Guide](#).



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## Managing potential side effects

During treatment with **ENHERTU**, side effects may occur and you should notify your healthcare provider as early as possible

**ENHERTU can cause serious, potentially fatal side effects. See pages 20-21 for the most important information you should know about ENHERTU.**

**The most common side effects of ENHERTU when used at the 5.4 mg/kg dose include:**

- Low white blood cell counts
- Nausea
- Low red blood cell counts
- Feeling tired
- Low platelet counts
- Increased liver function tests
- Vomiting
- Hair loss
- Constipation
- Low levels of blood potassium
- Decreased appetite
- Diarrhea
- Muscle or bone pain

The majority of side effects in people receiving ENHERTU were mild or moderate\*; however, some people may have serious side effects that could lead to death. It is important to call your doctor for medical advice about side effects.

\*Mild side effects are side effects you may have, but they show no outward signs or medical intervention may not be needed. Moderate side effects may require some medical intervention or may affect you as you do day-to-day activities.

These are not all of the possible side effects of ENHERTU. Call your doctor for medical advice about side effects.

You are encouraged to report side effects of ENHERTU to Daiichi Sankyo at **1-877-437-7763**. If you prefer to report these to the FDA, visit [www.FDA.gov/medwatch](https://www.fda.gov/medwatch) or call **1-800-FDA-1088 (1-800-332-1088)**.

**Find details about how you will receive ENHERTU on page 27 of this brochure.**

Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS, and click here for Medication Guide.](#)

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## What to tell your healthcare provider

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

- Have lung or breathing problems
- Have kidney problems. Your healthcare provider may follow you more closely. In clinical trials, more serious lung problems were seen in patients with certain kidney problems
- Have liver problems. Your healthcare provider may follow you more closely.
- 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.

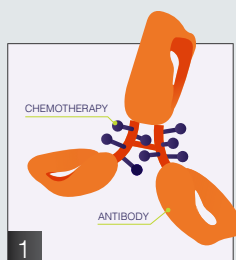
**Remember to call your healthcare provider right away for medical advice if you experience any side effects. It is important to manage any side effects you may have with your healthcare provider.**

Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS](#), and [click here for Medication Guide](#).

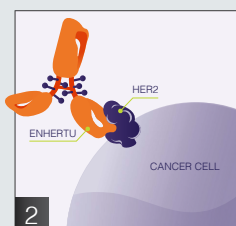
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## How ENHERTU is thought to work

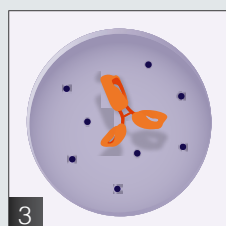
As a targeted treatment called an antibody-drug conjugate (ADC), ENHERTU is designed to work differently than traditional chemotherapies.



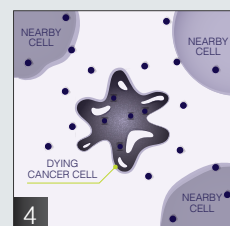
ENHERTU is made up of an antibody with the chemotherapy attached



The antibody part of ENHERTU targets and attaches to HER2 on the cancer cell



ENHERTU enters the cancer cell and the chemotherapy is released



The chemotherapy part of ENHERTU helps destroy the cancer cell as well as other cells nearby

Although ENHERTU is designed to target HER2 on cancer cells, it may affect some healthy cells. ENHERTU may not work for everyone.

### IMPORTANT SAFETY INFORMATION (cont'd)

**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.

**Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS](#), and [click here for Medication Guide](#).**


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## How will I receive ENHERTU?

**ENHERTU** is given as an intravenous (IV) infusion once every 3 weeks

You will receive an ENHERTU infusion either at your oncologist's office or at a nearby infusion center.



Your healthcare provider will give you medicines before your infusion to help prevent nausea and vomiting



The first ENHERTU infusion will take about 90 minutes so the healthcare provider can monitor any potential reactions



Future ENHERTU infusions should take about 30 minutes if your first infusion was well tolerated

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.

If you experience side effects, your doctor may reduce your dose, delay treatment, or completely stop treatment with ENHERTU.

### IMPORTANT SAFETY INFORMATION (cont'd)

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


Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS, and click here for Medication Guide.](#)

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## Support & resources

# ENHERTU4U may be able to help you access and afford treatment with **ENHERTU** after it has been prescribed

The ENHERTU4U program is designed to help you access and afford your prescribed ENHERTU treatment, including benefits reviews, prior authorization and/or claims appeal information, and paying for your prescription.\*



### ACCESS

ENHERTU4U is here to help your healthcare provider understand your insurance company's requirements for 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 may be able to help.

\*For eligible patients. Terms and conditions apply.

For more information about ENHERTU4U, please call 1-833-ENHERTU (1-833-364-3788) or scan the QR code to visit [ENHERTU4U.com](https://enherthu4u.com).

ENHERTU4U does not guarantee access or cost savings for patients prescribed ENHERTU.



## Connect with helpful resources



American Cancer Society  
[cancer.org](https://cancer.org)

The American Cancer Society does not endorse any product or service.

This is not an all-inclusive list of resources.



CancerCare®  
[cancercare.org](https://cancercare.org)



Cancer Support Community  
[cancersupportcommunity.org](https://cancersupportcommunity.org)



**Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information](#), including **Boxed WARNINGS**, and [click here for Medication Guide](#).**

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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 (such as 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:
  - 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.**

- **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 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 4 months after the last dose.

*Continued on next page*

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## Important Safety Information (cont'd)

**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.
- Your healthcare provider will give you medicines before your infusion to help prevent nausea and vomiting.
- 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.

### **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 when used at the 5.4 mg/kg dose include:**

- |                                  |                                 |
|----------------------------------|---------------------------------|
| • Low white blood cell counts    | • Hair loss                     |
| • Nausea                         | • Constipation                  |
| • Low red blood cell counts      | • Low levels of blood potassium |
| • Feeling tired                  | • Decreased appetite            |
| • Low platelet counts            | • Diarrhea                      |
| • Increased liver function tests | • Muscle or bone pain           |
| • Vomiting                       |                                 |

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. Call your doctor for medical advice about side effects. You may report side effects to Daiichi Sankyo at 1-877-437-7763 or to FDA at 1-800-FDA-1088.

*Continued on next page*

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## Important Safety Information (cont'd)

### What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

- ENHERTU was FDA approved for this use based on clinical studies 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.

**Please see accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide.**

**Please see additional Important Safety Information throughout and on pages 31-33, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS, and \[click here for Medication Guide.\]\(#\)](#)**

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Find out more about ENHERTU by speaking to your healthcare provider, visiting [ENHERTU.com/IHC3plus-tumors](https://www.enherthu.com/IHC3plus-tumors), or scanning the QR code.

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