

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



Is ENHERTU right for me?



What is ENHERTU?

ENHERTU® (fam-trastuzumab deruxtecan-nxki) is a prescription drug for people with:

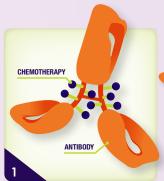
- HER2+ breast cancer that has spread to other parts of your body or cannot be removed by surgery
- And have already received at least 2 other prior treatments for HER2+ breast cancer





How is ENHERTU thought to work?

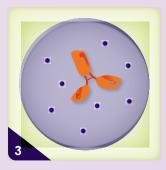




ENHERTU is made up of an antibody with a chemotherapy attached



The ENHERTU antibody targets and attaches to the HER2+ cancer cell



enters the cancer cell and the chemotherapy is released



The ENHERTU chemotherapy helps destroy the cancer cell

Although ENHERTU is designed to target HER2+ cancer cells, it may affect healthy cells.

ENHERTU may not work for everyone.

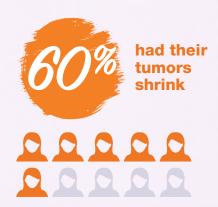
Select Important Safety Information (cont'd)

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.



The majority of people had their tumors shrink with ENHERTU





In a clinical study of 184 women, most people treated with ENHERTU (60%) saw their tumors shrink*†

- Some people (4.3%[‡]) achieved what is known as a complete response, meaning their tumor could not be seen on imaging tests
- Most people (56%) achieved a partial response, which means the tumor shrank by at least 30%

• 97% of people treated with ENHERTU had their tumors shrink, stop growing, or the growth of their tumors slowed^{||}

\$\| 97\%\$ is the disease control rate for the clinical study, which is the sum of the ORR and stable disease. In the study, 179 of 184 patients achieved a disease control rate.

Stable disease means that the tumor did not increase in size by more than 20% nor decrease in size by more than 30%.

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
- Coughing
- Feeling tired
- Swelling of your ankles or legs

- Irregular heartbeat
- Sudden weight gain
- Dizziness or feeling light-headed
- Loss of consciousness



^{*}The amount of people who had their tumors shrink is called the objective response rate (or ORR).

^{†111} of 184 people saw their tumors shrink.

[‡]8 of 184 people achieved a complete response.

^{§103} of 184 people achieved a partial response.

The majority of people had their tumors shrink with ENHERTU (cont'd)



Half of the people who responded to ENHERTU were able to maintain their response for nearly 15 months

In the same clinical study, half of the 111 people who responded to ENHERTU were able to maintain their response for 14.8 months or longer. However, how long responses lasted varied by person.



14.8 months is the median length of time people maintained their response to ENHERTU. This is called the duration of response. Median is the middle number in a group of numbers arranged from lowest to highest.

Half of the people who received ENHERTU lived without their cancer growing or spreading for more than 16 months

In the same clinical study, half of the 184 people who received ENHERTU lived without their cancer growing or spreading for more than 16.4 months. The median progression-free survival (PFS) is the length of time from the start of treatment that half of the people in the study had gone without disease progression.#



ENHERTU was FDA approved based on the clinical study results that showed how many people responded and how long they responded. The FDA has not reviewed the progression-free survival data. ENHERTU is still being studied to confirm these results.

Median PFS was 16.4 months.

This study only evaluated ENHERTU. There was no comparison of results to another treatment option for HER2+ metastatic breast cancer.

The median length of time patients were evaluated throughout the study was 11.1 months. The length of time varied for each patient and the last data patients were evaluated was August 1, 2019.

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.



A variety of people with HER2+ mBC responded to ENHERTU



In a clinical study of 184 people, 60% of people treated with ENHERTU had their tumor shrink.

ENHERTU was evaluated in 180 people from the study who were either hormone receptor positive (HR+) or hormone receptor negative (HR-)*

ENHERTU helped shrink tumors in:



66% of people who were HR-



*ENHERTU helped shrink tumors in 56 of 97 people who were HR positive and 55 of 83 people who were HR negative. There were 4 people in the clinical study whose HR status was not known.

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.



A variety of people with HER2+ mBC responded to ENHERTU (cont'd)



In the same clinical study of 184 people, ENHERTU was explored in 24 people with HER2+ mBC that had spread to the brain and was stable

of these 24 people had their non-brain tumors shrink[†]

Presence of brain metastases was noted but was not measured.

†14 of the 24 people saw their non-brain tumors shrink.



- **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.



What are the most common side effects of ENHERTU?



The most common side effects with ENHERTU, when used in people with breast cancer, include:

- Nausea
- Low white blood cell counts
- Low red blood cell counts
- Feeling tired
- Vomiting
- Hair loss
- Increased liver function tests

- Low platelet counts
- Constipation
- Decreased appetite
- Diarrhea
- Low levels of blood potassium
- Cough

These are not all the possible side effects of ENHERTU.

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 or call 1-800-FDA-1088 (1-800-332-1088).



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



ENHERTU can cause 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, like interstitial lung disease/pneumonitis, 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)
- Feeling tired
- Weight loss

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



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





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

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



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

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.

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



ENHERTU is taken alone without the need for other medicines to treat breast cancer





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

Most infusions take 30 minutes



The first infusion will take about 90 minutes so the doctor can see if there are any side effects or problems



Future infusions should only take about half an hour, if your first infusion was well tolerated

Select Important Safety Information (cont'd)

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).



ENHERTU is taken alone without the need for other medicines to treat breast cancer (cont'd)



Your healthcare provider can adjust your dose if you have side effects with ENHERTU

To help manage your side effects, your healthcare provider may:







Select Important Safety Information (cont'd)

- 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.



ENHERTU4U may be able to help you access and afford treatment with ENHERTU





ENHERTU4U is here to help your healthcare provider understand your insurance company's requirements for access to treatment with ENHERTU.



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 support from ENHERTU4U, please call 1-833-ENHERTU (1-833-364-3788) or visit ENHERTU4U.com.



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:

- 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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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.

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.

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.

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Important Safety Information (cont'd)



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 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 in people with breast cancer, include:

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

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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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.

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.

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



Connect with helpful resources





American Cancer Society

www.cancer.org



Living Beyond Breast Cancer

www.lbbc.org



Metavivor

www.metavivor.org



Share Cancer Support

www.sharecancersupport.org



Susan G. Komen

www.komen.org



For information about your ENHERTU treatment, visit **ENHERTU.com**.







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. 3. Ripley BA, Kelil T, Gill RR. Deciphering drug-induced interstitial lung disease. A mechanistic approach. Appl Radiol. 2016;45(4):9-18. 4. Kubo K. Azuma A. Kanazawa M. et al: Japanese Respiratory Society Committee, Consensus statement for the diagnosis and treatment of drug-induced lung injuries. Respir Investig. 2013;51(4):260-277. 5. Modi S, Saura C, Yamashita T, et al. Trastuzumab deruxtecan in previously treated HER2-positive breast cancer. N Engl J Med. 2020;382(7):610-621.



