A Guide to ENHERTU

For certain adults with HER2-low or HR+, HER2-ultralow, metastatic breast cancer (mBC)

Metastatic is defined as cancer that has spread to other parts of the body.
HER2, human epidermal growth factor receptor 2; HR+, hormone receptor-positive.
Not an actual patient.

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have:

- Human epidermal growth factor receptor 2 (HER2)-low breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received a prior chemotherapy
  - for metastatic disease, **or**
  - whose disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery).

- Hormone receptor (HR)-positive, HER2-low or HR-positive, HER2-ultralow, breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received one or more endocrine treatments for metastatic disease.

Your healthcare provider will perform a test to make sure ENHERTU is right for you.

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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ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

Not actual patients.

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Content guide

Your healthcare team 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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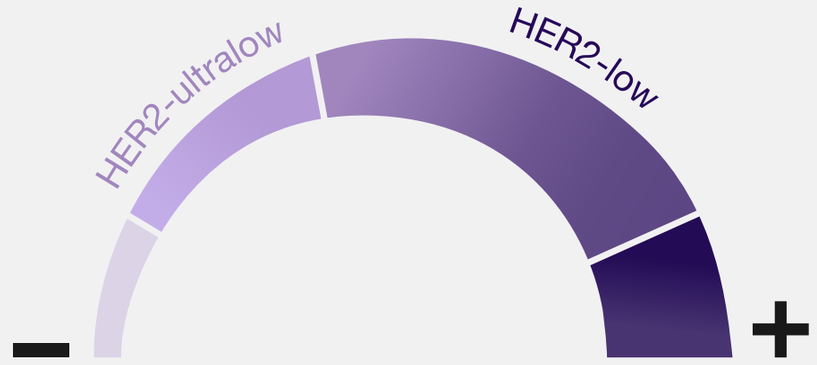
About HER2 status

If you were previously diagnosed with HER2-negative metastatic breast cancer, you may actually have low HER2 levels

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

In people with breast cancer, HER2 status used to be thought of like an on/off switch: HER2-positive or HER2-negative. Now it is thought to be more like a dimmer.



Some doctors now recognize HER2-low and HER2-ultralow as subsets of HER2-negative.

Having HER2-low or HER2-ultralow means that there is a low level of HER2 on cancer cells but not enough HER2 to be considered HER2-positive.

If your HER2-negative mBC stops responding to endocrine (hormone) treatment, ask your doctor if you have low levels of HER2.

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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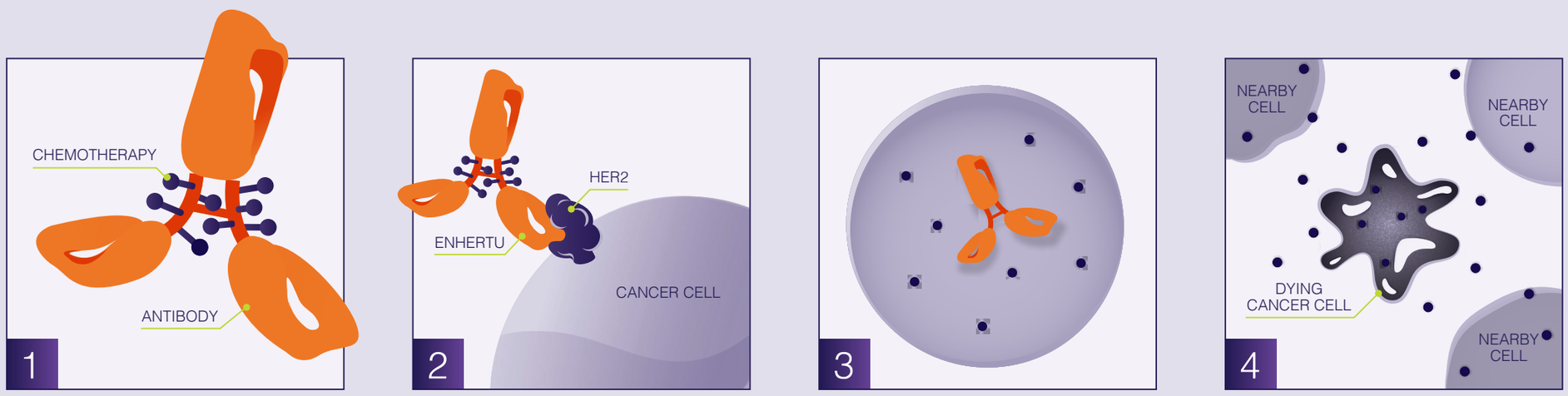
About HER2 status (cont'd)

Your doctor can evaluate your HER2 levels to determine if a therapy designed to target HER2 on cancer cells, like ENHERTU, is right for you.

If your doctor told you that you have HER2-negative mBC, ask if your HER2 immunohistochemistry (IHC) score could indicate a diagnosis of HER2-low or HER2-ultralow, mBC.

HER2 status is different than hormone receptor (HR) status. People with low levels of HER2 can be either HR positive or HR negative.

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)

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 trial 2024

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC **who received prior hormone treatment** in the metastatic setting and have not received chemotherapy for metastatic disease

ENHERTU was compared to chemotherapy in a clinical study of 866 adults who:

- Had low levels of HER2 proteins
- Had received at least one hormone treatment for metastatic disease

Of the 866 adults studied:

436 adults received ENHERTU

713 adults had HR+, HER2-low, mBC

Of the 713 adults, 359 received ENHERTU and 354 received chemotherapy.

430 adults received chemotherapy

153 adults had HR+, HER2-ultralow, mBC

Of the 153 adults, 77 received ENHERTU and 76 received chemotherapy.

Based on the results of the study,
ENHERTU is FDA approved for adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting.

HR+, hormone receptor-positive.

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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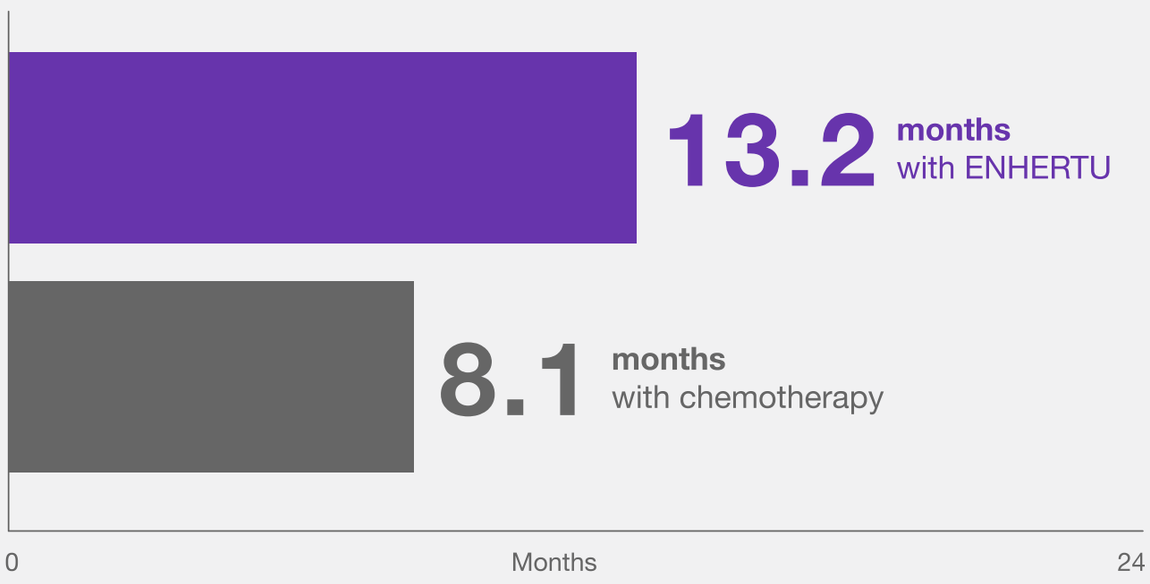
Clinical trial 2024 (cont'd)

Median progression-free survival

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting,

ENHERTU helped people live longer without their cancer growing or spreading compared to chemotherapy*†



Median progression-free survival is the amount of time that half of the people enrolled in the study were on treatment before their cancer started growing or spreading. See page 27 for more terms and definitions.

- **Primary results for the HER2-low population:** 359 people treated with ENHERTU lived a median of 13.2 months without their cancer growing or spreading and 354 people treated with chemotherapy lived a median of 8.1 months.
- **Exploratory results for the HER2-ultralow population:** 77 people treated with ENHERTU lived a median of 15.1 months without their cancer growing or spreading and 76 people treated with chemotherapy lived a median of 8.3 months‡

*Compared to chemotherapy, people who received ENHERTU had 36% lower risk of disease progression or death.
†Patients received physician's choice of chemotherapy. Out of 430 patients, 257 received capecitabine, 105 received nab-paclitaxel, and 68 received paclitaxel.
‡These study results were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.
HR+, hormone receptor-positive.

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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Clinical trial 2024 (cont'd)

Median overall survival

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting,

More than half of the people taking ENHERTU were still alive when the latest results were reported

>50%

The study is still ongoing.

At the time of analysis, more than half of patients taking chemotherapy were also still alive.

Median overall survival is the length of time, from either the date of diagnosis or the start of treatment, that half the people in a group are still alive. See page 27 for more terms and definitions.

HR+, hormone receptor-positive.

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.

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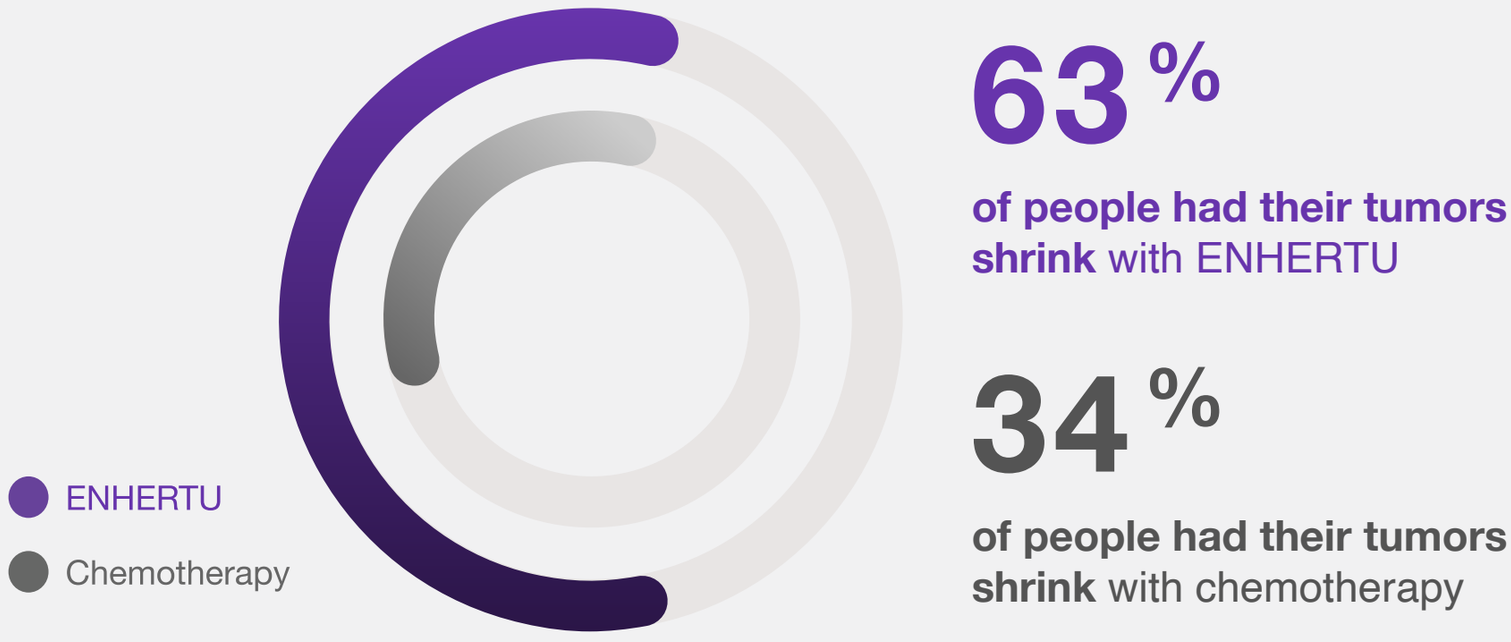
Overall response rate

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting,

The percentage of people who had their tumors shrink with ENHERTU and with chemotherapy*†



63%

of people had their tumors shrink with ENHERTU

34%

of people had their tumors shrink with chemotherapy

Overall response rate is the proportion of patients who have a partial or complete response to therapy. See page 27 for more terms and definitions.

- 2.5% (10 of 393) of people treated with ENHERTU and 0% (0 of 389) of people treated with chemotherapy achieved a complete response. A complete response means the tumors could not be seen on imaging tests†
- 60% (236 of 393) of people treated with ENHERTU and 34% (134 of 389) of people treated with chemotherapy achieved a partial response. A partial response means there was at least 30% tumor shrinkage†
- **Primary results for the HER2-low population:** Based on the people with measurable disease (326 people who received ENHERTU and 324 people who received chemotherapy), 62% (202 of 326) had their tumors shrink with ENHERTU and 35% (114 of 324) with chemotherapy
- **Exploratory results for the HER2-ultralow population:** Based on the people with measurable disease (67 people who received ENHERTU and 65 people who received chemotherapy), 66% (44 of 67) had their tumors shrink with ENHERTU and 31% (20 of 65) with chemotherapy†

*Based on the people with measurable disease (393 people who received ENHERTU and 389 people who received chemotherapy), 63% (246 of 393) had their tumors shrink with ENHERTU and 34% (134 of 389) with chemotherapy.

†These study results were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.

HR+, hormone receptor-positive.

IMPORTANT SAFETY INFORMATION (cont'd)

How will I receive ENHERTU? (cont'd)

- 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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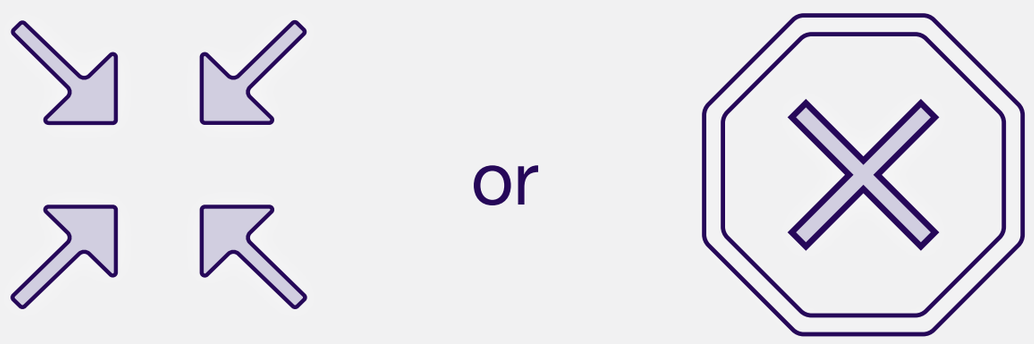
Additional results

Disease control rate

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting,

With ENHERTU, over 90% of people had their tumors*†:



Disease control rate is the percentage of people who have achieved complete response, partial response, or stable disease. Stable disease means tumors did not increase in size 20% or more or decrease in size 30% or more. See page 27 for more terms and definitions.

*92% (362 of 393) of people treated with ENHERTU achieved disease control.
†These study results were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.

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?"

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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Clinical trial 2022

In adults with either HR+ or HR– HER2-low mBC who **received chemotherapy** for metastatic disease

ENHERTU was compared to chemotherapy in a clinical study of 557 adults of different ages* and previous treatments who:

- Had low levels of HER2 proteins
- Had unresectable (cannot be removed with surgery) or mBC†
- Had already received chemotherapy for metastatic disease, or had the disease return during or within 6 months of completing adjuvant chemotherapy (after surgery)

Of the 557 adults studied:

373 adults received ENHERTU

184 adults received chemotherapy

494 adults had HR+ mBC

63 adults had HR– mBC

*Patients studied were 28 to 81 years of age.
†Patients with HR+ had received at least one hormonal therapy or were ineligible for hormonal therapy.

Median progression-free survival

ENHERTU nearly doubled the time people lived without their cancer growing or spreading (9.9 months) compared to chemotherapy (5.1 months)‡§

See page 27 for the definition of median progression-free survival and other terms and definitions.

- **331 people who were HR+** and treated with ENHERTU lived a median of 10.1 months without their cancer growing or spreading compared to a median of 5.4 months for 163 people treated with chemotherapy
- **The small group of 40 people included in this study who were HR–** and treated with ENHERTU lived a median of 8.5 months without their cancer growing or spreading, while the 18 people treated with chemotherapy lived a median of 2.9 months‖
  - Before the approval of ENHERTU for people with HER2-low mBC, these people might have been told by their healthcare providers that they had triple-negative breast cancer (ER–, PR–, and HER2-negative)

‡35% (130 of 373) of people treated with ENHERTU were alive at the time of data analysis without their cancer progressing, compared to 31% (57 of 184) of people treated with chemotherapy.
§Patients received physician's choice of chemotherapy. Out of 184 patients, 94 received eribulin, 37 received capecitabine, 19 received gemcitabine, 19 received nab-paclitaxel, and 15 received paclitaxel.
‖These study results in HR– patients were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.
ER–, estrogen receptor-negative; HR, hormone receptor; HR+, hormone receptor-positive; HR–, hormone receptor-negative; PR–, progesterone receptor-negative.

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.

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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Clinical trial 2022 (cont'd)

In adults with either HR+ or HR– HER2-low mBC who **received chemotherapy** for metastatic disease

Median overall survival

People treated with ENHERTU were alive a median of 23.4 months vs 16.8 months with chemotherapy*†

See page 27 for the definition of median overall survival and other terms and definitions.

*Patients received physician's choice of chemotherapy. Out of 184 patients, 94 received eribulin, 37 received capecitabine, 19 received gemcitabine, 19 received nab-paclitaxel, and 15 received paclitaxel.
†60% (224 of 373) of people treated with ENHERTU were alive at the time of data analysis, compared to 51% (94 of 184) of people treated with chemotherapy.

Overall response rate

52% of people had their tumors shrink with ENHERTU (16% with chemotherapy)‡§‖

See page 27 for overall response rate and other terms and definitions.

- 4% of people treated with ENHERTU and 1% of people treated with chemotherapy achieved a complete response§¶
- 49% of people treated with ENHERTU and 15% of people treated with chemotherapy achieved a partial response§#

‡Patients received physician's choice of chemotherapy. Out of 184 patients, 94 received eribulin, 37 received capecitabine, 19 received gemcitabine, 19 received nab-paclitaxel, and 15 received paclitaxel.
§These study results were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.
‖52% (195 of 373) of people treated with ENHERTU and 16% (30 of 184) people treated with chemotherapy had their tumors shrink.
¶4% (13 of 373) of people treated with ENHERTU and 1% (2 of 184) of people treated with chemotherapy achieved a complete response.
#49% (183 of 373) of people treated with ENHERTU and 15% (28 of 184) of people treated with chemotherapy achieved a partial response.

Additional results

Disease control rate: Nearly 90% of people treated with ENHERTU had their tumors either shrink or stop growing.††**

See page 27 for disease control rate and other terms and definitions.

**87% (325 of 373) of people treated with ENHERTU achieved disease control.
††These study results were based on an exploratory analysis, which was not intended to compare the two treatments. The study was also open-label, meaning that both the patients and trial investigators knew which treatment patients received. Therefore, the results could have been influenced by people switching to another treatment, leaving the study, or other factors. This means the results of the exploratory analysis cannot be fully explained and may not be the effect of the treatment. Each person's experience may differ. Speak with your doctor about what you may expect.
HR+, hormone receptor-positive; HR–, hormone receptor-negative.

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

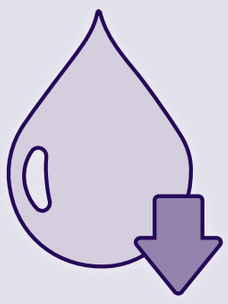
ENHERTU can cause serious side effects. Some serious or life-threatening side effects may affect your lungs, heart, or white blood cell count, affecting your ability to fight infection.

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

Lung problems, 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 (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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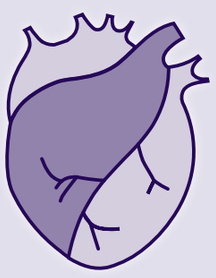
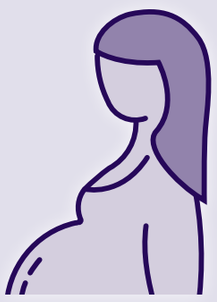
Potential side effects and how to help manage them (cont'd)



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

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.

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

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

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.

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**.

*Mild side effects are side effects you may have, but they may not show outward signs and 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.

There are steps you can take to help proactively manage some of ENHERTU side effects.
To learn more, visit **ENHERTU.com/safety/her2low**.

Please see full Important Safety Information on pages 23-25, and click here for full ENHERTU Prescribing Information, including Boxed WARNINGS, and click here for Medication Guide.

ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

Not actual patients.

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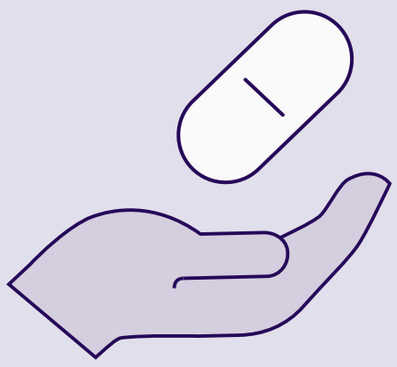
Receiving ENHERTU

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 treat the side effect, delay your dose, reduce your dose, or stop ENHERTU.

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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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**.

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

Connect with helpful resources

American Cancer Society
cancer.org

Living Beyond Breast Cancer
lbbc.org

Share Cancer Support
sharecancersupport.org

METAvivor
metavivor.org

Susan G. Komen
komen.org

This is not an all-inclusive list of resources.

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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.

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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
- 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

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.

*You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call 1-800-FDA-1088.*

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Important Safety Information (cont'd)

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have:

- HER2-low breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received a prior chemotherapy
  - for metastatic disease, **or**
  - whose disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery).
- Hormone receptor (HR)-positive, HER2-low or HR-positive, HER2-ultralow, breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received one or more endocrine treatments for metastatic disease.

Your healthcare provider will perform a test to make sure ENHERTU is right for you.

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

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Glossary

Below you will find definitions for terms related to metastatic breast cancer and ENHERTU that may be unfamiliar to you.

complete response: When tumors are not seen on imaging tests in response to treatment

disease control rate: The percentage of people who have achieved complete response, partial response, or stable disease

endocrine treatment: A type of treatment, also called hormone treatment, that involves adding, blocking, or removing hormones

estrogen receptor (ER): A cell protein that binds to estrogen, a type of hormone that may cause cells to grow

hormone receptor (HR): A cell protein that binds to a specific hormone and may cause cells to grow

human epidermal growth factor receptor 2 (HER2): A protein that tells cells to grow. When cells produce too much HER2, they can become cancerous

immunohistochemistry (IHC): A laboratory method that uses antibodies to check for certain markers, such as HER2, in a sample of tissue

intravenous (IV): A treatment received into a vein

median: The middle number in a set of numbers

metastatic: Cancer that has spread to other parts of the body

overall response rate: A percentage that measures the amount of patients who have a partial or complete response to therapy

overall survival: The length of time, from either the date of diagnosis or the start of treatment, that the people in a group are still alive

partial response: When there is at least 30% tumor shrinkage

progesterone receptor (PR): A cell protein that binds to progesterone, a type of hormone that may cause cells to grow

progression-free survival: The amount of time a patient is on a treatment without their cancer growing or spreading

stable disease: Cancer tumors that did not increase in size 20% or more or decrease in size 30% or more

unresectable: Cannot be removed with surgery

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Sign up for more support information.

Scan the QR code or visit
ENHERTU.com/support

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