A Guide to ENHERTU

for certain adults with **HER2-positive** 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.

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)-positive breast cancer that cannot be removed by surgery or has spread to other parts of the body (metastatic) in combination with pertuzumab as your first treatment. Your healthcare provider will perform a test to make sure ENHERTU in combination with pertuzumab is right for you.
- HER2-positive 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 anti-HER2 breast cancer treatment for metastatic disease or have breast cancer that has come back during or within 6 months of completing treatment for their early-stage breast cancer.

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

Whether you have already started on or are considering treatment with ENHERTU, this brochure is designed to help you understand your treatment plan.

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

Not an actual patient.

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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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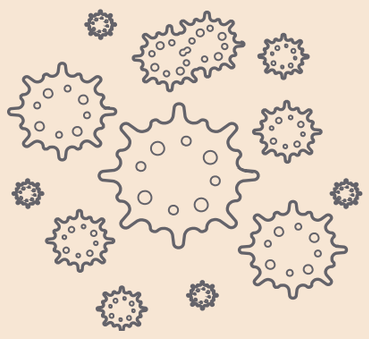
Understanding HER2-positive mBC

Up to 20% of people with mBC have high levels of HER2

HER2 is a protein that tells cells to grow. In HER2-positive mBC, the cancer cells have too much HER2, which leads to cancer growth.



These cells grow and divide faster than healthy cells, causing tumors to form.

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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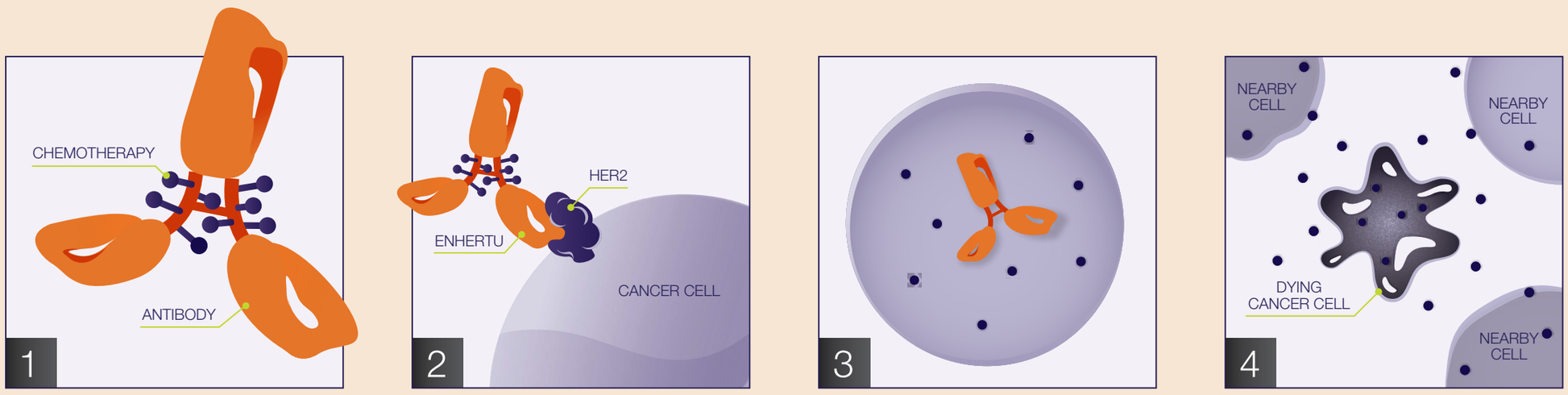
HER2+ mBC & ENHERTU (cont'd)

How is ENHERTU 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.

If you have not yet received a treatment for HER2-positive metastatic breast cancer, **ENHERTU can work with pertuzumab to target HER2 cancer cells.**

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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No prior treatment

In adults with HER2-positive mBC who **had not yet received their first treatment** for metastatic disease

The biggest breakthrough in **10 YEARS**

ENHERTU in combination with pertuzumab is **the biggest breakthrough** for people starting HER2-positive metastatic breast cancer treatment **in over a decade**.* This gives people a chance to live longer without their cancer advancing.

*Compared to a taxane-based chemotherapy, Herceptin® (trastuzumab), and pertuzumab combination. Read on to learn more.

Study design

ENHERTU with pertuzumab was compared to THP in a clinical study of adults with different ages† and hormone receptor statuses.

Of the adults in the 2 groups studied:

383 adults received ENHERTU + pertuzumab

387 adults received THP

Based on the results of this study, ENHERTU in combination with pertuzumab is FDA approved for adults with HER2-positive mBC who have not received prior therapy for their metastatic breast cancer.

†Patients studied were 20 to 88 years of age.
THP, taxane-based chemotherapy, Herceptin® (trastuzumab), and pertuzumab.

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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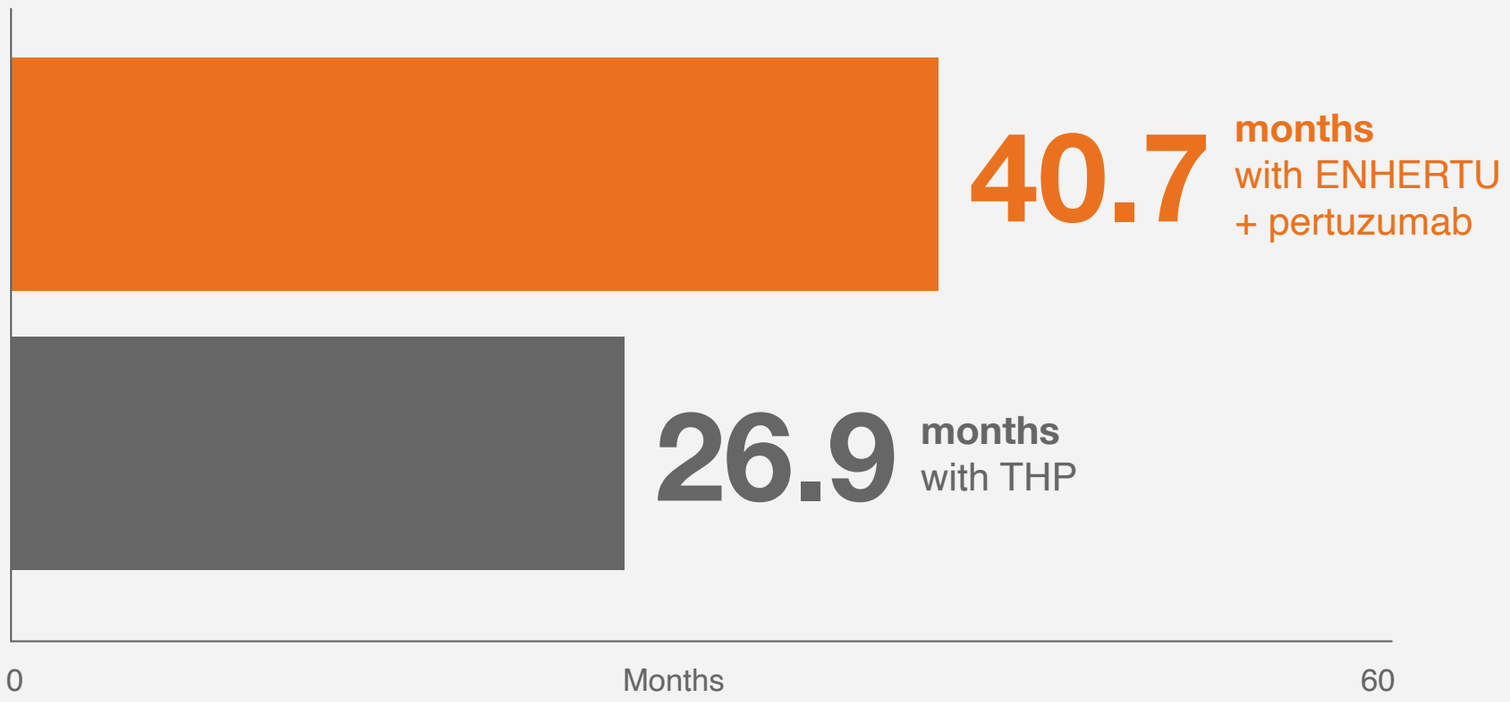
No prior treatment (cont'd)

Median progression-free survival

ENHERTU in combination with pertuzumab is **the first treatment combination to help people live longer without their cancer growing and spreading** compared with THP



Median progression-free survival is the amount of time from the start of treatment that half of the patients are alive without their cancer growing or spreading.

THP, taxane-based chemotherapy, Herceptin® (trastuzumab), and pertuzumab.

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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No prior treatment (cont'd)

Overall response rate*

Majority of tumors **shrink or disappear** from scans

87%
with ENHERTU in combination with pertuzumab

&

81%
with THP

Overall response rate is the proportion of patients who have a partial or complete response to therapy.

- 15% (56 of 374) of people achieved a complete response who received ENHERTU in combination with pertuzumab and 8% (30 of 371) of people who received THP. A complete response means the tumor could not be seen on imaging tests
- 72% (268 of 374) of people achieved a partial response who received ENHERTU in combination with pertuzumab and 73% (271 of 371) of people who received THP. A partial response means the tumor shrank by at least 30%

Additional results*

Disease control rate

With ENHERTU in combination with pertuzumab,
95% (356 of 374) 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.

*Not tested for statistical significance and not designed to show differences between treatments. Statistical significance describes a mathematical measure of difference between groups. The difference is statistically significant if it is greater than what might be expected to happen by chance alone.

THP, taxane-based chemotherapy, Herceptin® (trastuzumab), and pertuzumab.

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.

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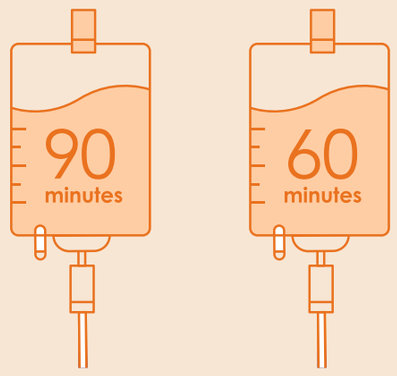
How will I receive ENHERTU?

For adults **receiving their first treatment** for mBC

ENHERTU and pertuzumab are given as intravenous (IV) infusions once every 3 weeks.

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

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



The first infusion of ENHERTU in combination with pertuzumab will take roughly 2.5 hours, with approximately 30 minutes between infusions, so your healthcare provider can monitor for any potential reactions.

Your ENHERTU infusion will take about 90 minutes and your pertuzumab infusion will take about 60 minutes.

Future ENHERTU and pertuzumab infusions should take about 30 to 60 minutes each if your first infusions were well tolerated.

You will receive ENHERTU and pertuzumab until your cancer has gotten worse or when you can no longer tolerate treatment.

If you miss a planned dose of ENHERTU with pertuzumab, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle.

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 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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Not actual patients.
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Previously treated

In adults with HER2-positive mBC **who had received prior treatment** for metastatic disease

Study design

ENHERTU was compared to ado-trastuzumab emtansine in a clinical study of 524 adults with different ages* and previous treatments who:

- Had positive levels of HER2 proteins
- Had breast cancer that was unresectable (cannot be removed with surgery) or metastatic[†‡§]
- Had already received a prior treatment for HER2-positive mBC or had cancer come back during or within 6 months of treatment after surgery

Of the 524 adults studied:

261 **adults received** ENHERTU

263 **adults received** ado-trastuzumab emtansine

*Patients studied were 20 to 83 years of age.
[†]Patients had various hormone receptor statuses.
[‡]Tumors that had spread (metastasized) to other parts of the body, including the liver, lungs, and bones.
[§]Including patients with tumors that had spread to the brain and were stable.

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 alone at the 5.4 mg/kg dose in people with metastatic breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors include:

- low white blood cell count
- 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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Previously treated (cont'd)

Progression-free survival

ENHERTU helped people live longer without their cancer growing or spreading compared with ado-trastuzumab emtansine

72% of people who received ENHERTU were more likely to be alive without their cancer progressing compared with ado-trastuzumab emtansine

Progression-free survival is the amount of time from the start of treatment that a person is alive without their cancer growing or spreading.

At the time of data analysis (May 2021), median progression-free survival was not yet reached for people receiving ENHERTU. This means that more than half of people who started treatment with ENHERTU were alive without their cancer growing or spreading. This compares to half of the people who started treatment with ado-trastuzumab emtansine who reached median progression-free survival at about 7 months before their cancer began to grow or spread.

- 67% (174 of 261) of people treated with ENHERTU were alive at the time of data analysis without their cancer progressing, compared with 40% (105 of 263) of people treated with ado-trastuzumab emtansine

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ENHERTU? (cont'd)
The most common side effects of ENHERTU, when used in combination with pertuzumab at the 5.4 mg/kg dose in people with HER2-positive metastatic breast cancer include:

- low white blood cell counts
- low red blood cell counts
- nausea
- increased liver function tests
- diarrhea
- low platelet counts
- low levels of blood potassium
- feeling tired
- hair loss
- vomiting
- upper respiratory tract infection
- constipation
- decreased appetite
- weight loss
- COVID-19
- muscle or bone pain
- stomach pain

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Previously treated (cont'd)

Overall survival

People receiving ENHERTU lived longer compared with people receiving ado-trastuzumab emtansine

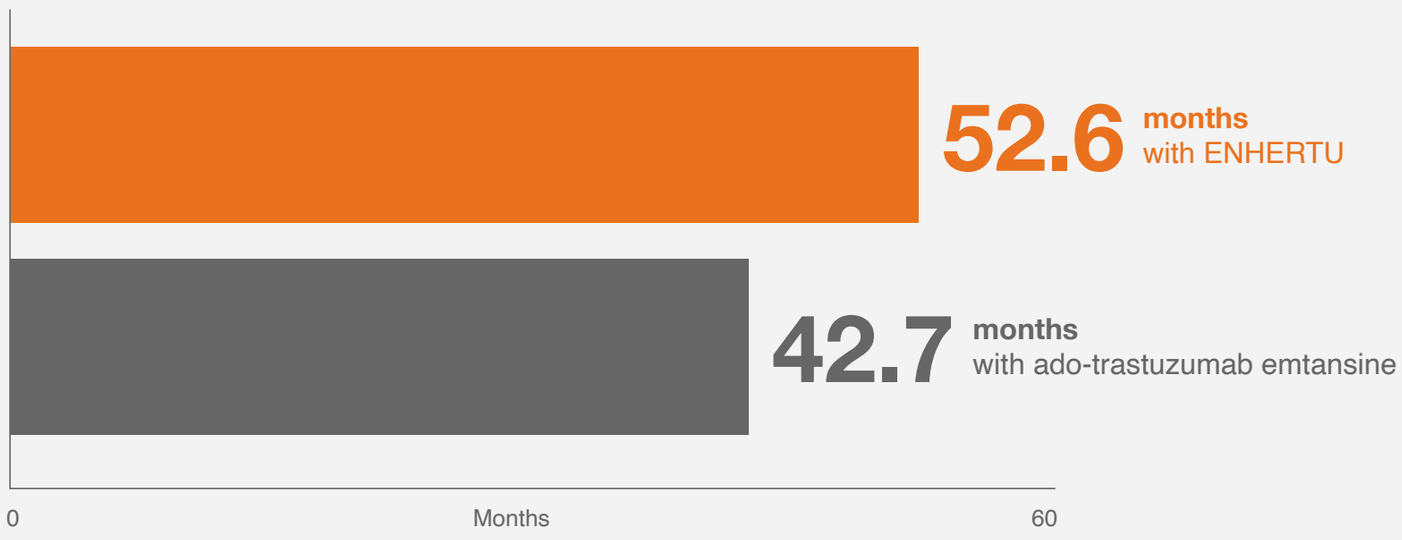
Overall survival data was not available in the initial assessment in May 2021, but positive data emerged in July 2022

> 50 %

At the time of updated data analysis, more than 50% of people receiving ENHERTU or ado-trastuzumab emtansine were still alive (July 2022)*

- ENHERTU reduced the risk of death in patients by 36% vs ado-trastuzumab emtansine
- 65% (170 of 261) of people treated with ENHERTU were alive at the time of this data analysis (median follow-up was 28.4 months), and 52% (138 of 263) of people treated with ado-trastuzumab emtansine were alive at the time of data analysis (median follow-up was 26.5 months)

Median overall survival with ENHERTU and ado-trastuzumab emtansine (November 2023)†



Median overall survival is the length of time, from either the day of diagnosis or the start of treatment, that half the patients in a group are still alive. A median is the middle number in a set of numbers.

*At the time of data analysis, since more than 50% of people receiving ENHERTU or ado-trastuzumab emtansine were still alive, the results could not be reported in months.

†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? (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 FDA at 1-800-FDA-1088.

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Overall response rate

In the first assessment, more people had their **tumors shrink with ENHERTU** than with ado-trastuzumab emtansine (May 2021)*

83%
with ENHERTU

&

36%
with ado-trastuzumab emtansine

Overall response rate is the proportion of patients who have a partial or complete response to therapy.

Of the people who responded to treatment†:

- 16% (39 of 248) of people achieved a complete response with ENHERTU and 8% (20 of 241) of people treated with ado-trastuzumab emtansine. A complete response means the tumor could not be seen on imaging tests
- 67% (166 of 248) of people achieved a partial response with ENHERTU and 28% (67 of 241) of people treated with ado-trastuzumab emtansine. A partial response means the tumor shrank by at least 30%

In an updated assessment (July 2022)‡:

- 82% of people had their tumors shrink with ENHERTU
- 37% of people had their tumors shrink with ado-trastuzumab emtansine

Of the people who responded to ENHERTU in the updated assessment:

- 21% (52 of 246) of people achieved a complete response with ENHERTU and 9% (21 of 240) of people treated with ado-trastuzumab emtansine
- 61% (150 of 246) of people achieved a partial response with ENHERTU and 28% (67 of 240) of people treated with ado-trastuzumab emtansine

*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.

†Based on the people in the first assessment with measurable disease (248 people who received ENHERTU and 241 people who received ado-trastuzumab emtansine). In the first assessment, 83% (205 of 248) of people had their tumors shrink with ENHERTU and 36% (87 of 241) of people with ado-trastuzumab emtansine.

‡Based on the people in the updated assessment with measurable disease (246 people who received ENHERTU and 240 people who received ado-trastuzumab emtansine). In the updated assessment, 82% (202 of 246) of people had their tumors shrink with ENHERTU and 37% (88 of 240) of people with ado-trastuzumab emtansine.

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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Additional results

Disease control rate

In the first assessment (May 2021), 98% (242 of 248) of people treated with ENHERTU had their tumors respond to treatment in at least one of the following ways:

Disease control rate is the percentage of people who have achieved complete response, partial response, or stable disease.*

*Not tested for statistical significance and not designed to show differences between treatments. Statistical significance describes a mathematical measure of difference between groups. The difference is statistically significant if it is greater than what might be expected to happen by chance alone.

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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Previously treated (cont'd)

How will I receive ENHERTU?

For adults **previously treated** for mBC

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 infusions to help prevent nausea and vomiting.

The first ENHERTU with infusion will take about 90 minutes so your healthcare provider can monitor for 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.

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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Side effects

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.

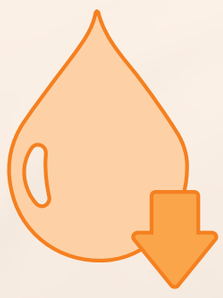
Pay special attention to new or worsening symptoms as they may be related to:

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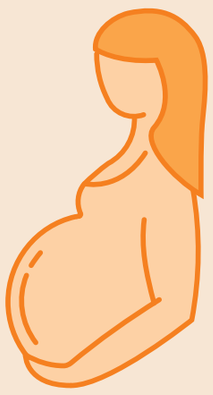
What is the most important information I should know about ENHERTU? (cont'd)

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.

Please see full Important Safety Information on pages 26, 27, and 29, 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 an actual patient.

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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 alone at the 5.4 mg/kg dose in people with metastatic breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors 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 most common side effects of ENHERTU, when used in combination with pertuzumab at the 5.4 mg/kg dose in people with HER2-positive metastatic breast cancer include:

- Low white blood cell counts
- Low red blood cell counts
- Nausea
- Increased liver function tests
- Diarrhea
- Low platelet counts
- Low levels of blood potassium
- Feeling tired
- Hair loss
- Vomiting
- Upper respiratory tract infection
- Constipation
- Decreased appetite
- Weight loss
- COVID-19
- Muscle or bone pain
- Stomach pain

The majority of side effects in people receiving ENHERTU or ENHERTU with pertuzumab 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. If you experience side effects, your doctor may treat the side effect, delay your dose, reduce your dose, or stop ENHERTU and/or pertuzumab.

*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 the possible side effects of ENHERTU. Call your doctor for medical advice about side effects. You are encouraged to report 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)**.

Useful tips may help you manage side effects. To learn more, visit **ENHERTU.com/mBC/safety**

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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 visit **ENHERTU4U.com**.

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

ENHERTU4U provides patients and their providers access and reimbursement support for ENHERTU. Reimbursement and access are not guaranteed.

Connect with helpful resources

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

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 alone at the 5.4 mg/kg dose in people with metastatic breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors 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

(continues on page 29)

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Important Safety Information (cont'd)

The most common side effects of ENHERTU, when used in combination with pertuzumab at the 5.4 mg/kg dose in people with HER2-positive metastatic breast cancer include:

- low white blood cell counts
- low red blood cell counts
- nausea
- increased liver function tests
- diarrhea
- low platelet counts
- low levels of blood potassium
- feeling tired
- hair loss
- vomiting
- upper respiratory tract infection
- constipation
- decreased appetite
- weight loss
- COVID-19
- muscle or bone pain
- stomach 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 FDA at 1-800-FDA-1088.

What is ENHERTU?

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

- human epidermal growth factor receptor 2 (HER2)-positive breast cancer that cannot be removed by surgery or has spread to other parts of the body (metastatic) in combination with pertuzumab as your first treatment. Your healthcare provider will perform a test to make sure ENHERTU in combination with pertuzumab is right for you.
- HER2-positive 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 anti-HER2 breast cancer treatment for metastatic disease or have breast cancer that has come back during or within 6 months of completing treatment for their early-stage breast cancer.

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

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

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 treatment

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

progression-free survival: The amount of time from the start of treatment that a person is alive 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.

For more support information, visit **ENHERTU.com/support**

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