

A Guide to ENHERTU for **early breast cancer**

For certain adults with HER2-positive early breast cancer who are starting ENHERTU followed by THP before surgery or starting ENHERTU alone after surgery

HER2, human epidermal growth factor receptor 2; THP, taxane-based chemotherapy (eg, paclitaxel), Herceptin® (trastuzumab), and pertuzumab.

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults with:

- Human epidermal growth factor receptor 2 (HER2)-positive stage II or stage III early breast cancer followed by a taxane, trastuzumab and pertuzumab (THP) before surgery. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

ENHERTU alone is a prescription medicine used to treat adults with:

- HER2-positive early breast cancer who have received trastuzumab (with or without pertuzumab) and taxane-based treatment before surgery and have cancer remaining in the tissue removed during surgery.

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

Please see full Important Safety Information on page 12, and [click here for full ENHERTU Prescribing Information](#), including **Boxed WARNINGS**, and [click here for Medication Guide](#).

Not an actual patient.

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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20 mg/mL INJECTION FOR INTRAVENOUS USE



Whether you are planning to start ENHERTU before or after surgery for HER2-positive early breast cancer, this brochure is designed to help you feel prepared and informed about your treatment plan.

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

Get more information about eBC at [**ENHERTU.com/understanding-ebc**](https://www.enhertu.com/understanding-ebc)

eBC, early breast cancer; HER2, human epidermal growth factor receptor 2.

Not actual patients.

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Your healthcare team can answer any further questions you may have.

Please see full Important Safety Information on page 12, and [click here for full ENHERTU Prescribing Information, including Boxed WARNINGS, and click here for Medication Guide.](#)

Before Surgery Dosing

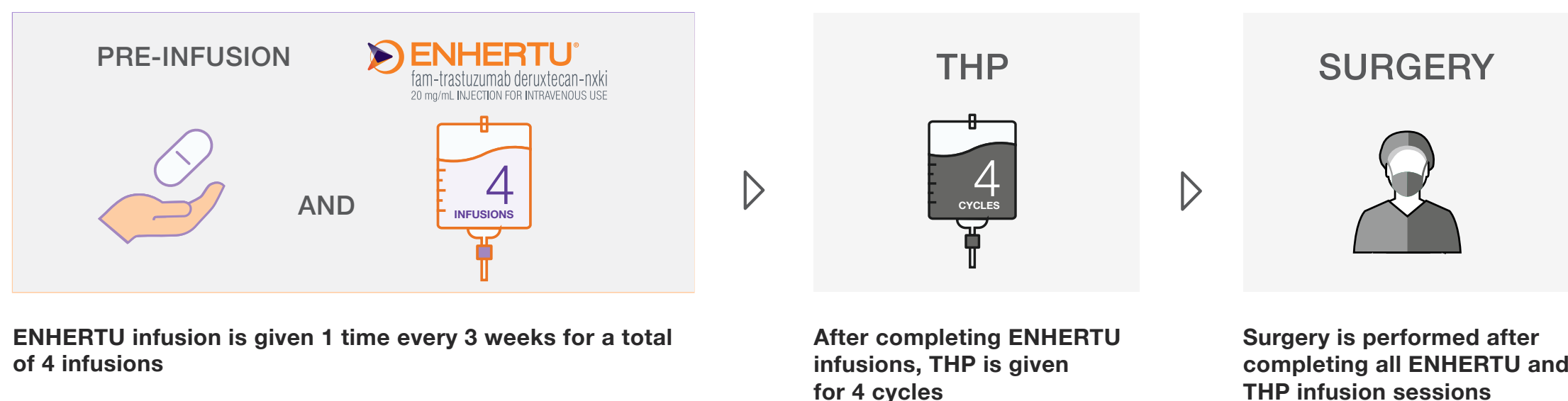
TREATING eBC BEFORE SURGERY

For certain adults with HER2-positive eBC who are starting treatment before surgery (neoadjuvant)

How will I receive ENHERTU followed by THP?

ENHERTU is given as an intravenous infusion at your oncologist's office or at a nearby infusion center.

You will receive your THP infusions after completing your ENHERTU infusions.



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

Your first ENHERTU infusion will take about **90 minutes** so the 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.

The goal of treatment before surgery is to help reduce the size of your tumor to make it easier to remove during surgery.

eBC, early breast cancer; HER2, human epidermal growth factor receptor 2; THP, taxane-based chemotherapy (eg, paclitaxel), Herceptin® (trastuzumab), and pertuzumab.

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.
- **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 and during treatment if needed. 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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Before Surgery Results

UNDERSTANDING **THE RESULTS**

ENHERTU followed by THP was studied in certain adults with HER2-positive early breast cancer who had not yet had breast cancer surgery.

ENHERTU followed by THP is the **biggest breakthrough** in more than 5 years for people with HER2-positive early breast cancer before they have surgery.*

ENHERTU followed by THP was evaluated in a clinical study of certain adults with HER2-positive early breast cancer.

OF THE ADULTS IN THE 2 GROUPS STUDIED:

1

One group received
ENHERTU followed by THP

2

The other group received
ddAC followed by THP

*Based on a clinical trial where 67% of patients who received ENHERTU followed by THP achieved pathological complete response (pCR) compared with 56% who received dose-dense doxorubicin and cyclophosphamide followed by THP.

Not an actual patient.

More study participants who received ENHERTU followed by THP before surgery achieved pCR than those who received chemotherapy followed by THP



67%

of people achieved
pCR with ENHERTU → THP

Pathological complete response (pCR) means that after pre-surgery treatment there are no signs of cancer in the tissue removed during surgery.



56%

of people achieved
pCR with ddAC → THP

Your pCR status helps doctors evaluate the effectiveness of your treatment and plan next steps.

● ENHERTU → THP ● ddAC → THP

The standard chemotherapy regimen used in this study was ddAC followed by THP.

If you have questions about ENHERTU or your treatment plan, talk with your healthcare provider about what is right for you.

ddAC, dose-dense doxorubicin + cyclophosphamide; HER2, human epidermal growth factor receptor 2; THP, taxane-based chemotherapy (eg, paclitaxel), Herceptin® (trastuzumab), and pertuzumab.

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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After Surgery Dosing

TREATING eBC AFTER SURGERY

For certain adults with HER2-positive eBC who have completed pre-surgery treatment and surgery (post-neoadjuvant)

How will I receive ENHERTU?

ENHERTU is given as an intravenous infusion at your oncologist's office or at a nearby infusion center.



ENHERTU infusion is given 1 time every 3 weeks for a total of 14 infusions

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

Your first ENHERTU infusion will take about **90 minutes** so the 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.

The goal of treatment after surgery is to help destroy any cancer cells that may remain after surgery and help lower the chances of the cancer coming back.

eBC, early breast cancer; HER2, human epidermal growth factor receptor 2.

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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After Surgery Results

UNDERSTANDING THE RESULTS

ENHERTU was studied in certain adults with HER2-positive early breast cancer who had completed pre-surgery treatment and surgery.

ENHERTU is the **biggest breakthrough** in more than 7 years among targeted therapies for the after-surgery treatment of HER2-positive early breast cancer.*

ENHERTU was compared to trastuzumab emtansine in a clinical study of eligible adults.

OF THE ADULTS IN THE 2 GROUPS STUDIED:

1

One group received
ENHERTU

2

The other group received
trastuzumab emtansine

*Based on a post-neoadjuvant clinical trial where patients who received ENHERTU had a 53% lower chance of cancer returning compared with trastuzumab emtansine.

Not an actual patient.

53% of people who received ENHERTU were more likely to be alive without their cancer returning compared with trastuzumab emtansine

At 3 years, **92%** (756 of 818) of people showed **no signs of cancer** when treated with ENHERTU and **84%** (684 of 817) of people showed no signs of cancer when treated with trastuzumab emtansine†

†The 3-year data were not tested for statistical significance and did not show differences between treatments. Statistical significance describes the 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.

If you have questions about ENHERTU or your treatment plan, talk with your healthcare provider about what is right for you.

HER2, human epidermal growth factor receptor 2.

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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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:

Not actual patients.

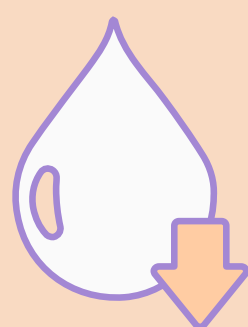


Lung problems that may be severe, life-threatening, or that may lead to death

Call or see your healthcare provider right away if you develop any of the following signs and symptoms or if these symptoms get worse:

- Cough
- Trouble breathing or shortness of breath
- Fever
- Other new or worsening breathing symptoms (such as chest tightness, wheezing)

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



Low white blood cell count (neutropenia)

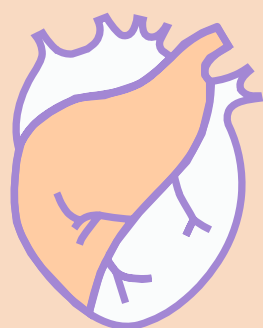
- Low white blood cell counts are common with ENHERTU and can sometimes be severe
- Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose
- Tell your healthcare provider right away if you develop any signs or symptoms of an infection or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

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

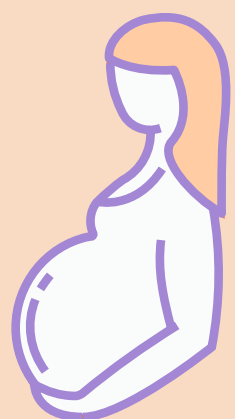


Heart problems that may affect your heart's ability to pump blood

Your healthcare provider will check your heart function before starting treatment with ENHERTU and during treatment if needed. 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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Side Effects (cont'd)

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 9-10 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 HER2-positive breast cancer and other 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 alone at the 5.4 mg/kg dose followed by THP, in people with HER2-positive stage II or stage III early breast cancer, include:

- low red blood cell counts
- increased liver function tests
- low white blood cell counts
- nausea
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs
- diarrhea
- hair loss
- feeling tired
- rash
- muscle or bone pain
- low levels of blood potassium
- constipation
- vomiting
- sores in or around your mouth
- decreased appetite

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.

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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 and during treatment if needed. 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.
- For the treatment of early breast cancer:
 - Before surgery, ENHERTU is given 1 time every three weeks (21-day treatment cycle) for 4 cycles followed by THP for 4 cycles.
 - After HER2-targeted treatment and surgery, ENHERTU is given 1 time every three weeks (21-day treatment cycle) for 14 cycles.
- 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 HER2-positive breast cancer and other solid tumors include:

- | | |
|----------------------------------|---------------------------------|
| • low white blood cell counts | • hair loss |
| • nausea | • constipation |
| • low red blood cell counts | • low levels of blood potassium |
| • feeling tired | • decreased appetite |
| • low platelet counts | • diarrhea |
| • increased liver function tests | • muscle or bone pain |
| • vomiting | |

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Important Safety Information (cont'd)

The most common side effects of ENHERTU when used alone at the 5.4 mg/kg dose followed by THP, in people with HER2-positive stage II or stage III early breast cancer, include:

- low red blood cell counts
- increased liver function tests
- low white blood cell counts
- nausea
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs
- diarrhea
- hair loss
- feeling tired
- rash
- muscle or bone pain
- low levels of blood potassium
- constipation
- vomiting
- sores in or around your mouth
- decreased appetite

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.

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults with:

- Human epidermal growth factor receptor 2 (HER2)-positive stage II or stage III early breast cancer followed by a taxane, trastuzumab and pertuzumab (THP) before surgery. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

ENHERTU alone is a prescription medicine used to treat adults with:

- HER2-positive early breast cancer who have received trastuzumab (with or without pertuzumab) and taxane-based treatment before surgery and have cancer remaining in the tissue removed during surgery.

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

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

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Glossary

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

early breast cancer (eBC): Cancer that has not spread beyond the breast or the nearby lymph nodes; includes Stage 0, I, II, and IIIa breast cancers

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 infusion: A treatment method of putting fluids, including medications, into the bloodstream through a vein

neoadjuvant: A type of cancer treatment, such as chemotherapy, radiation therapy, or hormone therapy, that is given to shrink the tumor before the main treatment (usually surgery)

pathological complete response (pCR): Means that after pre-surgery treatment there are no signs of cancer in the tissue removed during surgery. PCR status helps doctors evaluate the effectiveness of treatment and plan next steps

post-neoadjuvant: Additional cancer treatment given after the main treatment (usually surgery) to lower the risk that the cancer will come back

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A black and white photograph of two women in a clothing store. The woman on the left is smiling and looking towards the camera, wearing a denim shirt. The woman on the right is wearing sunglasses and adjusting them, looking slightly away from the camera. They are standing in front of a rack of clothes.

To sign up for more
support information, visit
[ENHERTU.com/support](https://enhertu.com/support)

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