ENHERTU4U Patient Authorization Form

ENHERTU® 4U
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

Patient Information

First Name: _____ Last Name: _____ DOB: ____/____/____

Address: _____

City: _____ State: _____ ZIP: _____

Home Phone #: _____ Mobile Phone #: _____ Email: _____

Patient Authorization

I authorize my health care providers (HCPs) and staff, my health plan, and my pharmacies to use and share Protected Health Information (my "Information") with AstraZeneca and Daiichi Sankyo (AZ/DSI) and its affiliates, as well as its contractors. My Information includes my prescription-related health records, Information about my health care plan benefits, demographic, contact, and any other Information bearing on my health. My Information may be used to verify treatment and payment decisions with my HCPs; investigate and assist with coordination of coverage for ENHERTU; coordinate prescription fulfillment and financial assistance; and perform internal analysis at AZ/DSI to better meet patient needs. I understand and agree that AZ/DSI may contact me by mail, email, and telephone. I understand that federal privacy laws may not protect my Information once it is disclosed; however, AZ/DSI agrees to protect my Information by using and disclosing it only for purposes specified. I understand that I can refuse to sign this Authorization and that this will not affect my treatment or payment for treatment, insurance coverage, or eligibility for benefits. However, if I do not sign this Authorization, I will not be able to receive ENHERTU4U support. I understand that I may cancel this Authorization at any time by calling 1-833-ENHERTU (1-833-364-3788). I understand that any such cancellation will not apply to any Information already used or disclosed based on this Authorization prior to their receipt of the cancellation. This Authorization expires two (2) years from the date signed, unless a shorter period is required by state law.

Print Legally Authorized Representative Name

_____

(I understand that ENHERTU4U can send me text messages generated by an automated dialer if I provide my mobile number and that text messaging rates may apply. I also understand that consent is not required to make a purchase.)

**Not Required.*

Which best describes you? ☐ I am a patient ☐ I am a legally authorized representative Relationship to patient: _____

Communication preference: ☐ Email ☐ Text ☐ Both*

ENHERTU Patient Savings Program

The ENHERTU Patient Savings Program is designed to facilitate access to ENHERTU. By providing my Authorization, I allow my health care providers, insurance companies and pharmacies to use and share my health care Information with the ENHERTU Patient Savings Program so that I can participate in this savings program. My health Information may be seen by AstraZeneca and Daiichi Sankyo (AZ/DSI) and companies working on their behalf for this savings program.

Optional Services

I understand that I may also receive ongoing information and support related to my condition, including treatment information. This may include AZ/DSI, or a third party working on their behalf, contacting me regarding ENHERTU support programs that may be of interest to me. Information provided by AZ/DSI does not take the place of talking to your health care provider about your treatment or condition. AZ/DSI or third parties working on their behalf will not sell or rent your personal information. If, in the future, you no longer want to receive these materials or calls, or you want to report a medication side effect, please call **1-877-437-7763**. Please visit https://dsi.com/privacy-notice to review our Privacy Notice.

☐ Yes, I would like additional information.

Communication preference: ☐ Email ☐ Text ☐ Both*

(I understand that ENHERTU4U can send me text messages generated by an automated dialer if I provide my mobile number and that text messaging rates may apply. I also understand that consent is not required to make a purchase.)

**Not Required.*

Signature of Patient/Legally Authorized Representative

Sign Here _____ Date: _____

1-833-ENHERTU (1-833-364-3788) **www.ENHERTU4U.com** **1-866-760-5917**

Please complete form, sign, and fax all pages to 1-866-760-5917.

Please see Important Safety Information on page 2, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Important Safety Information

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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.

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.
- For the treatment of metastatic breast cancer, HER2-mutant non-small cell lung cancer, gastric cancer or other HER2-positive solid tumors:
  - 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 HER2-positive, HER2-Low and HER2-Ultralow 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 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 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
- increased levels of blood bilirubin
- stomach pain

The most common side effects of ENHERTU, when used alone at the 6.4 mg/kg dose in people with HER2-positive gastric or GEJ adenocarcinoma, include:

- low red blood cell counts
- low white blood cell counts
- low platelet counts
- nausea
- decreased appetite
- increased liver function tests
- feeling tired
- diarrhea
- low levels of blood potassium
- vomiting
- constipation
- increased levels of blood bilirubin
- fever
- hair loss

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.
- 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.

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

Please see Important Safety Information on pages 2-3, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Important Safety Information (cont'd)

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- 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.
- non-small cell lung cancer (NSCLC) that has a certain mutation in the HER2 gene and cannot be removed by surgery or has spread to other parts of your body (metastatic), and who have received a prior treatment. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
  - ENHERTU was FDA approved for this use based on a clinical study that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results.
- stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that is HER2-positive and has spread to areas near your stomach (locally advanced) or that has spread to other parts of your body (metastatic), and who have received a prior trastuzumab-based regimen.
- solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
  - ENHERTU was FDA approved for this use based on clinical studies that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results.

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

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

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

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