Introducing

ENHERTU®

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

A Specifically Designed ADC That Addresses a Key Unmet Need for Some Patients Previously Treated for HER2+ Unresectable or Metastatic Breast Cancer

Join us for a LIVE broadcast!

You are invited to join your peers for an exciting live broadcast event featuring an expert-led discussion. This live broadcast program will allow you to be among the first to explore ENHERTU®, a newly approved antibody-drug conjugate with demonstrated efficacy in adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.*

This program will cover:

- A newly approved therapy option for these patients
- Results from the Phase 2 clinical trial, DESTINY-Breast01
- Key safety considerations for ENHERTU
- Dosage and administration of ENHERTU

*This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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<th>Live Broadcast Details:</th>
<th>REGISTRATION:</th>
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<tr>
<td>Wednesday, February 5, 2020</td>
<td>To register for this live broadcast, please RSVP to the representative program host:</td>
<td>01/29/2020</td>
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<tr>
<td>7:00 PM Eastern</td>
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The intended audience for this program is US healthcare professionals.

This program is being sponsored by Daiichi Sankyo, Inc. and AstraZeneca. The speaker is being compensated for the presentation. The program is not CME accredited and may not be used for CME accreditation. In accordance with PhRMA guidelines, spouses or other guests are not permitted to attend company-sponsored programs. Please be advised that information such as your name and the value and purpose of any educational item, meal, or other items of value you may receive may be publicly disclosed. If you are licensed in any state or other jurisdiction, or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceutical companies, please identify yourself so that compliance with such requirements can be ensured.

Important Safety Information

Indication

ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY

- Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.
- Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.

Contraindications

None.

Please see Important Safety Information and accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.
Embryo-Fetal Toxicity (continued)

Advise female patients of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU.

Adverse Reactions

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresetable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J01. ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, pleural effusion, and pulmonary edema. Pulmonary edema occurred in 1% of patients treated with ENHERTU. The most frequent adverse reactions occurred in >2% associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 15% of patients treated with ENHERTU. The most frequent adverse reactions associated with dose reduction were fatigue, nausea, and neutropenia.

Use in Specific Populations

- **Pregnancy:** ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU.

- **Lactation:** There are no data regarding the presence of ENHERTU in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.

- **Females and Males of Reproductive Potential:** Pregnancy testing: Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU. Contraception: Females: ENHERTU can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose. Males: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose. Infertility: ENHERTU may impair male reproductive function and fertility.

- **Pediatric Use:** Safety and effectiveness of ENHERTU have not been established in pediatric patients.

- **Geriatric Use:** Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were >65 years and 5% were >75 years. No overall differences in efficacy were observed between patients >65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged >65 years (53%) as compared to younger patients (42%).

- **Hepatic Impairment:** In patients with moderate hepatic impairment, due to the potential for increased exposure, closely monitor for increased toxicities related to ENHERTU.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc. at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

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