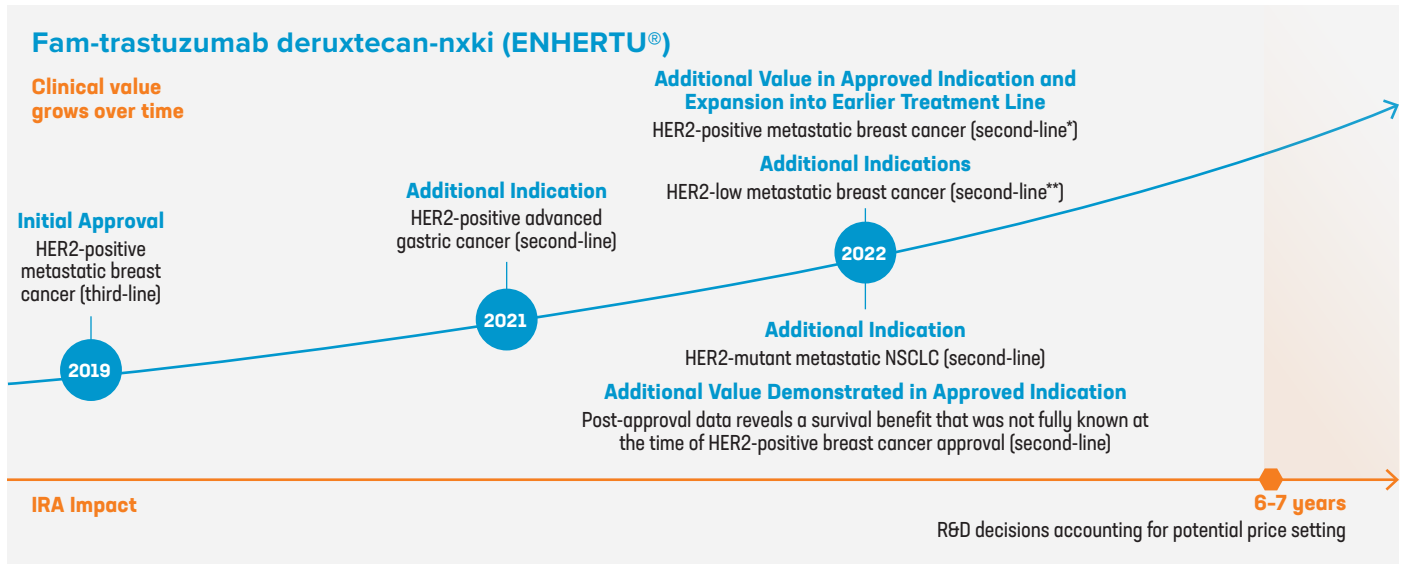


# Fam-trastuzumab deruxtecan-nxki | ENHERTU®

In 2019, the FDA granted trastuzumab deruxtecan<sup>1</sup> accelerated approval for patients with hard-to-treat metastatic breast cancer who test positive for the human epidermal growth factor receptor 2 (HER2) and have received two or more prior lines of anti-HER2-based treatment. Approximately one in five breast cancers have a mutation that makes excess HER2 protein, which promotes the growth of cancer cells. HER2-positive breast cancers are an aggressive form of breast cancer.<sup>1</sup> Trastuzumab deruxtecan is a HER2-directed antibody-drug conjugate, a class of targeted cancer medicine that binds to specific proteins on target cells and attacks those cells directly.<sup>2</sup> The therapy has shown clinical benefit in other types of cancer that express certain levels of the HER2 protein, in addition to breast cancer. Ongoing research continues to study trastuzumab deruxtecan in other HER2-positive cancers.<sup>3</sup>



**Additional Indication (January 2021):** Approved to treat patients with advanced HER2-positive gastric or gastroesophageal junction adenocarcinoma previously treated with a trastuzumab-based regimen. Gastric cancer is frequently diagnosed in the advanced stage and patients often have poor outcomes, with only 5% surviving beyond five years. In a clinical study supporting this approval, trastuzumab deruxtecan demonstrated a 41% reduction in the risk of death versus chemotherapy.<sup>4</sup>

**Additional Value in Initial Indication and Expansion into Earlier Treatment Line (May 2022):** Converted the initial approval in metastatic HER2-positive breast cancer from accelerated to traditional approval and broadened its use to an earlier treatment line (from third-line to second-line\*). In a clinical study supporting this expanded indication, trastuzumab deruxtecan showed a 72% reduction in the risk of disease progression or death versus another anti-HER2 treatment.<sup>5</sup>

**Additional Indication (August 2022):** Approved to treat patients with HER2-low metastatic breast cancer after prior treatment with chemotherapy.\*\* Study data revealed patients treated with trastuzumab deruxtecan lived a median of 10.1 months without their cancer growing, nearly twice as long as those treated with standard chemotherapy; and lived a median of 23.9 months, about six months longer overall.<sup>6,7</sup> This was the first approved therapy targeted to patients with HER2-low breast cancer, a newly defined subset of previously HER2-negative breast cancer.<sup>8</sup> Prior to this approval, only people with breast cancer whose tumor cells produce high levels of HER2 (also called HER2-positive) had been shown

to benefit from drugs that target HER2. This critical post-approval research revealed that patients with this historically difficult form of the disease could be treated with HER2-targeted therapy, fundamentally changing the way these cancers are classified and treated.<sup>9</sup>

**Additional Indication (August 2022):** Granted accelerated approval to treat patients with unresectable or metastatic HER2-mutant non-small cell lung cancer (NSCLC) cancer who have received prior therapy. This aggressive form of NSCLC more commonly impacts younger patients who have previously had limited treatment options and poor prognosis. This marks the first HER2-directed treatment option for patients with this specific type of lung cancer.<sup>10</sup>

**Additional Value Demonstrated in Approved Indication (December 2022):** Post-approval clinical study data revealed a survival improvement in patients with HER2-positive breast cancer. These patients lived a median of 28.8 months, nearly two years longer without their disease progressing compared to those on another anti-HER2 treatment.<sup>11</sup> Historically, patients with HER2-positive breast cancer often experience disease progression, underscoring the importance of the availability of treatment options that improve survival and delay disease progression.<sup>12</sup>

<sup>1</sup>Full US generic name: fam-trastuzumab deruxtecan-nxki

\*The broadening of this indication included use after one prior anti-HER2-based regimen in the metastatic, or in the neoadjuvant or adjuvant settings and experienced a disease recurrence within six months of completing treatment

\*\*Indication included use after prior chemotherapy in the metastatic setting or after disease recurrence during or within six months of completing adjuvant treatment

## Fam-trastuzumab deruxtecan-nxki | ENHERTU® (continued)

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- 8 U.S. Food and Drug Administration. "FDA Approves First Targeted Therapy for HER2-Low Breast Cancer." <https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-her2-low-breast-cancer>. Published August 5, 2022. Accessed June 13, 2023.
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- 10 Daiichi-Sankyo. "ENHERTU® Approved in the U.S. as the First HER2 Directed Therapy for Patients with Previously Treated HER2 Mutant Metastatic Non-Small Cell Lung Cancer." <https://daiichisankyo.us/press-releases/-/article/enhertu-approved-in-the-u-s-as-the-first-her2-directed-therapy-for-patients-with-previously-treated-her2-mutant-metastatic-non-small-cell-lung-cancer>. Published August 11, 2022. Accessed June 13, 2023.
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