# FDA Approves Enhertu for All Types of HER2-Positive Tumors

Overall response rates were around 50% for people with several types of advanced cancer.

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On April 5, the Food and Drug Administration (FDA) granted accelerated approval of Enhertu (fam-trastuzumab deruxtecan) for the treatment of patients with inoperable or metastatic HER2-positive solid tumors, regardless of location. The indication is for people who have already tried other systemic therapies and have no satisfactory alternative treatment options.

"Until the approval of trastuzumab deruxtecan, patients with metastatic HER2-positive solid tumors have had limited treatment options," Funda Meric-Bernstam, MD, of the University of Texas MD Anderson Cancer Center, said in a news release. "Based on the clinically meaningful response rates seen across clinical trials, this tumor-agnostic approval means that patients may now be treated with a HER2-directed medicine."

Enhertu, from Daiichi Sankyo and AstraZeneca, is an antibody-drug conjugate. The antibody (trastuzumab), which targets HER2—a protein that promotes cancer cell growth—carries a chemotherapy payload directly to cancer cells. Enhertu was first approved for advanced HER2-positive breast cancer in December 2019. It was later approved for HER2-low breast cancer. Additional indications were added for HER2-positive stomach cancer in 2021 and HER2-positive non-small-cell lung cancer (NSCLC) in 2022.

Now, the FDA has further expanded the indication to include unresectable or metastatic HER2-positive solid tumors anywhere in the body. This is important because less common cancers may not get their own clinical trials.

The latest approval is supported by data from nearly 200 adults with previously treated inoperable or metastatic HER2-positive tumors who were enrolled in three multicenter trials. DESTINY-Lung01 (NCT03505710) enrolled patients with NSCLC, DESTINY-CRC02 (NCT04744831) enrolled people with colorectal cancer and DESTINY-PanTumor02 (NCT04482309) enrolled people with solid tumors regardless of location. Treatment was administered by IV infusion every three weeks until disease progression or unacceptable toxicity.

Objective response rates—indicating tumor shrinkage—were 53% in the lung cancer trial, 47% in

the colorectal cancer trial and 51% in the pan-tumor trial. The median duration of response was 6.9 months, 5.5 months and 19.4 months, respectively. The pan-tumor results were reported at last year's American Society of Clinical Oncology Annual Meeting. Overall response rates ranged from 58% for endometrial cancer and 50% for cervical cancer down to just 4% for pancreatic cancer. Better response rates were observed for tumors with higher HER2 expression levels.

Treatment with Enhertu is generally safe, though side effects are common. The most frequent adverse effects include decreased white blood cell counts, decreased platelet counts, anemia and fatigue. The product label includes warnings about interstitial lung disease or pneumonitis (lung inflammation) and heart problems. Enhertu can cause fetal harm if used during pregnancy.

Drugs that receive accelerated approval based on overall response rates are expected to undergo further testing to confirm that they offer clinical benefits, such as delayed disease progression or improved survival, and the FDA can rescind the approval if they fail to measure up.

Click here for full prescribing information for Enhertu.
Click here for a Cancer Health feature on antibody-drug conjugates.

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