

# FDA approves Enhertu in the early-stage, HER2-positive breast cancer setting

Market Event Summary

# Trastuzumab deruxtecan expands into early breast cancer

## Event

- The FDA has **approved Enhertu (trastuzumab deruxtecan) for neoadjuvant and adjuvant use in select patients with HER2-positive early-stage breast cancer**; the May 2026 approval marks Enhertu's expansion into a curative-intent setting.
- In the **neoadjuvant setting**, Enhertu followed by trastuzumab, pertuzumab, and paclitaxel (THP) **improved pathologic complete response (pCR) rates** (67.3% vs. 56.3%,  $P = 0.003$ ) versus dose-dense doxorubicin and cyclophosphamide followed by THP (**DESTINY-Breast11**).
- In the **adjuvant setting**, Enhertu **improved invasive disease-free survival (iDFS)** versus Kadcyra (trastuzumab emtansine) (3-year iDFS: 92.4% vs. 83.7%, HR: 0.47,  $P < 0.0001$ ) in patients with residual invasive disease and at high risk of recurrence (**DESTINY-Breast05**).
- **Regulatory filings** in Europe and Japan based on DESTINY-Breast-05 are under review. Approvals in these regions are expected in 2026.

## Background

- **HER2-positive breast cancer accounts for ~15-20% of cases**, with a subset of early-stage patients still experiencing recurrence despite standard therapy.
- **Current treatment** includes chemotherapy plus trastuzumab ± pertuzumab, with Kadcyra used post-neoadjuvant in residual disease.
- **Residual disease** and **recurrence** are significant **unmet needs** in HER2-positive early-stage breast cancer, particularly in high-risk patients.

## Clarivate's takeaways



### Reshaping HER2-positive early-stage treatment paradigms

Conventional chemotherapies and earlier HER2-targeted agents dominate the treatment of HER2-positive early-stage disease. Enhertu's particularly strong efficacy in tumor eradication and recurrence outcomes establishes a new clinical benchmark and is expected to reshape clinical practice in early-stage breast cancer.



### Rapid displacement in high-risk populations

We believe Enhertu will displace Kadcyra as the preferred option for patients with residual disease following neoadjuvant HER2-targeted therapy who remain at high risk of recurrence, given the particularly strong outcomes for adjuvant Enhertu. Kadcyra will retain a role in lower-risk patients.



### Constraints

Lower tolerance for life-threatening toxicities in the curative-intent setting amplifies safety concerns. As a result, interstitial lung disease (ILD) remains a key safety consideration that is likely to limit broad early adoption, particularly in the adjuvant setting where treatment duration is longer.

While neoadjuvant use may offer advantages, including shorter treatment duration, broader uptake may be limited by the lack of predictive biomarkers, immature long-term outcomes, and uncertainty in post-neoadjuvant sequencing. The absence of prospective data following trastuzumab deruxtecan treatment failure further complicates treatment decisions and may delay adoption.

# About the author



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Dr. Walker has more than 12 years' experience in the pharmaceutical field. She has authored thought-leadership articles covering a broad range of pharmaceutical-industry-relevant topics and therapeutic areas, including the flagship Drugs to Watch article. She holds a Ph.D. in cell biology and genetics from the University of Manchester and was a Wellcome postdoctoral fellow at the University College London Institute of Healthy Ageing.

## Clarivate coverage of breast cancer

- Breast Cancer | [Disease Landscape & Forecast | G7](#)
- Breast Cancer | [Current Treatment: Physician Insights | US](#), exploring the current prescribing trends among medical oncologists treating breast cancer
- Breast Cancer | [Current Treatment: Treatment Sequencing | US](#), presenting surveyed medical oncologists' most frequent treatment sequences for breast cancer
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