17 September 2026
EMADOC-1700519818-3437927
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Enhertu

trastuzumab deruxtecan

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Enhertu. The marketing authorisation holder for this medicinal product is Daiichi Sankyo Europe GmbH.

The CHMP adopted a new indication as follows:

> Early breast cancer
>
> Enhertu as monotherapy is indicated for the adjuvant treatment of adult patients with resected HER2-positive breast cancer who have residual invasive disease after neoadjuvant taxane-based and HER2-targeted treatment (for biomarker-based patient selection, see section 4.2).

For information, the full indications for Enhertu will be as follows:

> **Early breast cancer**
>
> **Enhertu as monotherapy is indicated for the adjuvant treatment of adult patients with resected HER2-positive breast cancer who have residual invasive disease after neoadjuvant taxane-based and HER2-targeted treatment (for biomarker-based patient selection, see section 4.2).**
>
> Metastatic breast cancer
>
> Enhertu in combination with pertuzumab is indicated for the first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer (for biomarker-based patient selection, see section 4.2).
>
> Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens.
>
> *HER2-low and HER2-ultralow breast cancer*

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic

- hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment (see sections 4.2 and 5.1).
- HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy (see section 4.2).

Non-small cell lung cancer (NSCLC)

Enhertu as monotherapy is indicated for the treatment of adult patients with advanced NSCLC whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy.

Gastric cancer

Enhertu as monotherapy is indicated for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Other unresectable or metastatic solid tumours

Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory treatment options (see sections 4.4 and 5.1; for biomarker-based patient selection, see section 4.2).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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