25 June 2026
EMADOC-1700519818-3269360
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Datroway

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On 25 June 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 Datroway. The marketing authorisation holder for this medicinal product is Daiichi Sankyo Europe GmbH.

The CHMP adopted a new indication as follows:

> Datroway as monotherapy is indicated for the first-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy (see section 5.1).

For information, the full indications for Datroway will be as follows:[2]

> **Datroway as monotherapy is indicated for the first-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy (see section 5.1).**
>
> Datroway as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting (see section 5.1).

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.

[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.

[2] New text in bold.

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