



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2019
EMA/CHMP/615141/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Kadcyla

trastuzumab emtansine

On 14 November 2019, 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 Kadcyla. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to the existing indication as follows:²

“Early Breast Cancer (EBC)”

Kadcyla, as a single agent, is indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.

Metastatic Breast Cancer (MBC)

Kadcyla, as a single agent, is indicated for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for locally advanced or metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.”

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

¹ Summaries 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**

