30 January 2025
EMA/CHMP/28954/2025 Rev. 1[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Datroway[3]

datopotamab deruxtecan

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Datroway, intended for the treatment of breast cancer. The applicant for this medicinal product is Daiichi Sankyo Europe GmbH.

Datroway will be available as a 100 mg powder for concentrate for solution for infusion. The active substance of Datroway is datopotamab deruxtecan, an antineoplastic agent (ATC code: L01FX35). Datopotomab deruxtecan is a monoclonal antibody-drug conjugate that binds to TROP2-expressing tumour cells and undergoes internalisation and intracellular cleavage. This results in the release of deruxtecan in target cells, which causes DNA damage and apoptotic cell death.

The benefit of Datroway is prolonged progression-free survival compared to chemotherapy, as shown in a phase 3 randomised open-label study in patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer, following one or two prior lines of systemic therapy.

The most common side effects are stomatitis, nausea, fatigue, alopecia, constipation, vomiting, dry eye, keratitis, anaemia, decreased appetite, increased aspartate transferase (AST), rash, diarrhoea, neutropenia and increased alanine aminotransferase (ALT).

The full indication is:

> 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).

Datroway should be prescribed and supervised by physicians experienced in the use of cancer treatments.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] This document was modified on 10 February 2025 to clarify the sentence describing the benefits of the medicine
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[3] Previously known as Datopotamab deruxtecan Daiichi Sankyo

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.