EMA/CHMP/119530/2022 Rev 1
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Padcev

enfortumab vedotin

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Padcev, intended for the treatment of adult patients with urothelial cancer.[2] The applicant for this medicinal product is Astellas Pharma Europe B.V.

Padcev will be available as a powder for concentrate for solution for infusion (20 mg and 30 mg). The active substance of Padcev is enfortumab vedotin, an antibody drug conjugate (ATC code: L01FX13) that induces cytotoxicity in cancer cells by binding to the nectin-4 target on the cell surface and forming an ADC-nectin-4 complex. With the internalization and release of the drug component, the cycle cell is interrupted and the cells die.

The benefits of Padcev are its superiority in terms of overall survival and progression free survival compared with chemotherapy. The most common side effects are severe skin reactions, hyperglycaemia and peripheral neuropathy.

The full indication is:

> Padcev as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor (see section 5.1)

Padcev should be prescribed by physicians experienced in the treatment of cancer.

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 made available in all official European Union languages after 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] The CHMP had initially adopted an opinion on 16 December 2021. During the decision-making process further safety information was brought to the attention of the Committee. Following a request from the European Commission, the CHMP readopted its opinion on 24 February 2022, taking into account the latest information.

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