27 June 2024
EMA/CHMP/267474/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Balversa

erdafitinib

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Balversa, intended for the treatment of urothelial carcinoma harbouring susceptible FGFR3 genetic alterations. The applicant for this medicinal product is Janssen-Cilag International N.V.

Balversa will be available as 3 mg, 4 mg and 5 mg film-coated tablets. The active substance of Balversa is erdafitinib, an antineoplastic, protein kinase inhibitor (ATC code: L01EN01) that inhibits the fibroblast growth factor receptor (FGFR) tyrosine kinases. Deregulation of FGFR3 signalling has been implicated in the pathogenesis of urothelial cancer and FGFR inhibition has shown antitumour activity in FGFR-expressing cells.

The benefits of Balversa are its superiority in terms of overall survival and progression free survival compared to chemotherapy, as seen in a phase 3, randomised controlled open-label study in patients with advanced urothelial cancer with FGFR gene aberrations. The most common side effects are hyperphosphataemia, diarrhoea and stomatitis.

The full indication is:

> Balversa as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting (see section 5.1).

Balversa should be prescribed by physicians experienced in the use of anticancer therapies.

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

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