22 April 2022
EMA/CHMP/164312/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tabrecta

capmatinib

On 22 April 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 Tabrecta, intended for treatment of patients with advanced non-small cell lung cancer (NSCLC) harbouring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping.

The applicant for this medicinal product is Novartis Europharm Limited.

Tabrecta will be available as 150 mg and 200 mg film-coated tablets. The active substance of Tabrecta is capmatinib, a MET inhibitor (ATC code: L01EX17) which blocks MET phosphorylation and MET-dependent downstream signalling.

The benefits of Tabrecta are its objective response rate and response duration in patients with NSCLC harbouring alterations leading to METex14 skipping. The most common side effects are peripheral oedema, nausea, fatigue, vomiting, dyspnoea and decreased appetite.

The full indication is:

> Tabrecta as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring alterations leading to mesenchymal epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.

Tabrecta should be prescribed by physicians experienced in the use of anticancer medicinal products.

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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