EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2016
EMA/CHMP/498981/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cabometyx

cabozantinib

On 21 July 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cabometyx, intended for the treatment of advanced renal cell carcinoma (RCC). The applicant for this medicinal product is Ipsen Pharma.

Cabometyx will be available as 20 mg, 40 mg and 60 mg film-coated tablets. The active substance of Cabometyx is cabozantinib, a protein kinase inhibitor (ATC code: L01XE26) that inhibits multiple receptor tyrosine kinases implicated in tumour growth and angiogenesis, pathologic bone remodelling, drug resistance, and metastatic progression of cancer.

Cabometyx led to a statistically significant improvement in progression-free survival (PFS) compared with everolimus: PFS was 7.4 months with Cabometyx versus 3.8 months with everolimus [HR=0.58 (0.45, 0.74), p<0.0001)]. A planned interim analysis of Overall Survival (OS) was conducted at the time of the PFS analysis that did not reach the interim boundary for statistical significance (HR=0.68 [0.51, 0.90], p=0.006). In a subsequent unplanned interim analysis of OS, a statistically significant improvement was demonstrated for patients randomized to Cabometyx as compared with everolimus (median of 21.4 months vs. 16.5 months; HR=0.66 [0.53, 0.83], p=0.0003.

The most common side effects are diarrhoea, fatigue, nausea, decreased appetite, palmar-plantar erythrodysaesthesia syndrome (PPES), hypertension, vomiting, weight decreased, and constipation.

The full indication is: “Cabometyx is indicated for the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.” Therapy with Cabometyx should be initiated by a physician experienced in the administration 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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