21 July 2016
EMA/CHMP/480541/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kisplyx

lenvatinib

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 Kisplyx, intended for the treatment of patients with unresectable advanced or metastatic renal cell carcinoma (RCC). The applicant for this medicinal product is Eisai Europe Ltd.

Kisplyx will be available as 4 mg and 10 mg hard capsules. The active substance of Kisplyx is lenvatinib, a tyrosine kinase inhibitor (ATC code: L01XE29) that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors, in addition to other proangiogenic and oncogenic pathway-related receptor tyrosine kinases.

Kisplyx was shown to improve progression-free survival (PFS) in a randomized part of a Phase Ib/II study when used with everolimus (median 14.6 [95% CI: 5.9-20.1] months) compared with everolimus used alone (median 5.5 [95% CI: 3.5-7.1] months) with a HR of 0.40 (95% CI: 0.24, 0.68; p<0.001). The treatment effect of the combination was also supported by a post-hoc retrospective independent blinded review of scans with median PFS of 12.8 [95% CI: 7.4-17.5] months compared with everolimus used alone (median 5.6 [95% CI: 3.6-9.3] months) with a HR of 0.45 (95% CI: 0.26, 0.79; p=0.003).

The most common side effects are diarrhoea, fatigue, decreased appetite, vomiting, nausea and hypertension. Severe diarrhoea occurred at a higher frequency in the combination group than in the everolimus group.

The full indication is: "Kisplyx is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy." It is proposed that Kisplyx treatment should be initiated and supervised by a healthcare professional 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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