14 October 2021
EMA/CHMP/551957/2021
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Kisplyx

lenvatinib

On 14 October 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Kisplyx. The marketing authorisation holder for this medicinal product is Eisai GmbH.

The CHMP adopted an extension to the existing indication as follows:[2]

> Kisplyx is indicated for the treatment of adults with advanced renal cell carcinoma (RCC):
>
> - **in combination with pembrolizumab, as first-line treatment (see section 5.1).**
> - in combination with everolimus, following one prior vascular endothelial growth factor (VEGF)-targeted therapy (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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] New text in bold

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