



14 October 2021
EMA/CHMP/565583/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Lenvima

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 Lenvima. The marketing authorisation holder for this medicinal product is Eisai GmbH.

The CHMP adopted a new indication as follows:²

Differentiated Thyroid Carcinoma (DTC)

Lenvima as monotherapy is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

Hepatocellular Carcinoma (HCC)

Lenvima as monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy (see section 5.1).

Endometrial Carcinoma (EC)

Lenvima in combination with pembrolizumab is indicated for the treatment of adult patients with advanced or recurrent endometrial carcinoma (EC) who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and are not candidates for curative surgery or radiation.

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

