26 March 2015
EMA/CHMP/156546/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lenvima

lenvatinib

On 26 March 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lenvima, intended for the treatment of adult patients with differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma. Lenvima was designated an orphan medicinal product on 26 April 2013. The applicant for this medicinal product is Eisai Europe Ltd.

Lenvima will be available as 4 mg and 10 mg hard capsules. The active substance of Lenvima is lenvatinib, a protein kinase inhibitors (ATC code: L01XE29). Lenvatinib selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors in addition to other proangiogenic and oncogenic pathway-related receptor tyrosine kinases. By blocking these enzymes, lenvatinib can cut off the blood supply that keeps cancer cells growing and reduce the growth of cancer cells.

The benefits with Lenvima are its ability to improve progression-free survival among patients with radioiodine-refractory differentiated thyroid cancer in comparison with placebo. The most common side effects are hypertension, diarrhoea, decreased appetite, weight decreased, fatigue, nausea, proteinuria, stomatitis, vomiting, dysphonia, headache, and palmar-plantar erythrodysaesthesia syndrome (PPE).

The full indication is: “the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI)”.

It is proposed that Lenvima 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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