EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2021
EMA/CHMP/87640/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lextemy

bevacizumab

On 25 February 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lextemy, intended for the treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix. The applicant for this medicinal product is Mylan IRE Healthcare Limited.

Lextemy will be available as a 25 mg/ml concentrate for solution for infusion. The active substance of Lextemy is bevacizumab, a monoclonal antibody (ATC code: L01XC07). It binds to vascular endothelial growth factor (VEGF), the key driver of vasculogenesis and angiogenesis, thereby inhibiting the binding of VEGF to its receptors on the surface of endothelial cells. Neutralising the biological activity of VEGF reduces vascularisation of tumours, normalises remaining tumour vasculature, and inhibits the formation of new tumour vasculature, thereby inhibiting tumour growth.

Lextemy is a biosimilar medicinal product. It is highly similar to the reference product Avastin (bevacizumab), which was authorised in the EU on 12 January 2005. Data show that Lextemy has comparable quality, safety and efficacy to Avastin (bevacizumab). More information on biosimilar medicines can be found here.

The full indication is:

> Lextemy in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum.
>
> Lextemy in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer. For further information as to human epidermal growth factor receptor 2 (HER2) status, please refer to section 5.1.
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> Lextemy in combination with capecitabine is indicated for first-line treatment of adult patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and

[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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anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Lextemy in combination with capecitabine. For further information as to HER2 status, please refer to section 5.1.

Lextemy, in addition to platinum-based chemotherapy, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

Lextemy, in combination with erlotinib, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations (see section 5.1).

Lextemy in combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer.

Lextemy, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of adult patients with advanced (International Federation of Gynecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer (see section 5.1).

Lextemy, in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix (see section 5.1).

It is proposed that Lextemy be prescribed by physicians experienced in the use of antineoplastic 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.