EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2018
EMA/CHMP/852740/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zirabev

bevacizumab

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zirabev, intended for the treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer and carcinoma of the cervix. The applicant for this medicinal product is Pfizer Europe MA EEIG.

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

Zirabev 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 Zirabev has comparable quality, safety and efficacy to Avastin. More information on biosimilar medicines can be found here.

The full indication is:

> "Zirabev in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum.
>
> Zirabev 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.
>
> Zirabev, 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.
>
> Zirabev in combination with interferon alfa-2a is indicated for first line treatment of adult patients

[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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with advanced and/or metastatic renal cell cancer.

Zirabev, 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 Zirabev be prescribed by physicians experienced in the treatment of cancer.

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.