24 July 2025
EMA/222568/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eyluxvi

aflibercept

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eyluxvi, intended for the treatment of adults with neovascular (wet) age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DME) and visual impairment due to myopic choroidal neovascularisation (myopic CNV).

The applicant for this medicinal product is Biolitec Pharma Limited Zweigniederlassung Jena.

Eyluxvi will be available as a 40 mg/ml solution for injection in vials. The active substance of Eyluxvi is aflibercept, an antineovascularisation agent (ATC code: S01LA05). Aflibercept is a recombinant fusion protein consisting of the extracellular domains of human VEGF receptor 1 and 2 fused to the Fc portion of human IgG1. By acting as a soluble decoy for the natural VEGF receptors, aflibercept inhibits their activation, thereby reducing angiogenesis.

Eyluxvi is a biosimilar medicinal product. It is highly similar to the reference product Eylea (aflibercept), which was authorised in the EU on 22 November 2012. Data show that Eyluxvi has comparable quality, safety and efficacy to Eylea. More information on biosimilar medicines can be found here.

The full indication is:

> Eyluxvi is indicated for adults for the treatment of
>
> - neovascular (wet) age-related macular degeneration (AMD) (see section 5.1),
> - visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) (see section 5.1),
> - visual impairment due to diabetic macular oedema (DME) (see section 5.1),

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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- visual impairment due to myopic choroidal neovascularisation (myopic CNV) (see section 5.1).

Eyluxvi must only be administered by a qualified physician experienced in administering intravitreal injections.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.