19 June 2025
EMA/CHMP/193205/2025
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Vgenfli

aflibercept

On 19 June 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 Vgenfli, intended for the treatment of 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 Zakłady Farmaceutyczne Polpharma S.A.

Vgenfli will be available as 40 mg/ml solution for injection in pre-filled syringes and vials. The active substance of Vgenfli is aflibercept, an anti-neovascularisation 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.

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

The full indication is:

> Vgenfli 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

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- visual impairment due to myopic choroidal neovascularisation (myopic CNV) (see section 5.1).

Vgenfli 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.