20 July 2023
EMA/CHMP/299233/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yesafili

aflibercept

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yesafili, intended for the treatment of neovascular (wet) age-related macular degeneration, 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 Viatris Limited.

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

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

The full indication is:

> Yesafili is indicated for adults for the treatment of:
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> - 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),
> - visual impairment due to myopic choroidal neovascularisation (myopic CNV) (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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Yesafili 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 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.