24 June 2021
EMA/CHMP/321116/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Byooviz

ranibizumab

On 24 June 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 Byooviz, intended for the treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, proliferative diabetic retinopathy, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), and visual impairment due to choroidal neovascularisation.

The applicant for this medicinal product is Samsung Bioepis NL B.V.

Byooviz will be available as a 10 mg/ml solution for injection. The active substance of Byooviz is ranibizumab, a monoclonal antibody fragment (ATC code: S01LA04) which modulates angiogenesis by inhibiting vascular endothelial growth factor A.

Byooviz is a biosimilar medicinal product. It is highly similar to the reference product Lucentis, which was authorised in the EU on 22/01/2007. Data show that Byooviz has comparable quality, safety and efficacy to Lucentis. More information on biosimilar medicines can be found here.

The full indication is:

> Byooviz is indicated in adults for:
>
> - The treatment of neovascular (wet) age-related macular degeneration (AMD)
> - The treatment of visual impairment due to diabetic macular oedema (DME)
> - The treatment of proliferative diabetic retinopathy (PDR)
> - The treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)
> - The treatment of visual impairment due to choroidal neovascularisation (CNV).

[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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Byooviz must be administered by a qualified ophthalmologist experienced in 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.