21 July 2022
EMA/CHMP/644170/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vabysmo

faricimab

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vabysmo, intended for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DME). The applicant for this medicinal product is Roche Registration GmbH.

Vabysmo will be available as a 120 mg/ml solution for injection. The active substance of Vabysmo is faricimab, a bispecific antibody that neutralises both angiopoietin-2 and VEGF-A. By dual inhibition of Ang-2 and VEGF-A, faricimab reduces vascular permeability and inflammation, inhibits pathological angiogenesis and restores vascular stability which are associated with the increased retinal thickness observed in nAMD and DME.

The main benefit of Vabysmo is the improvement in visual acuity as measured in four phase III, randomised, double-masked, active comparator-controlled clinical studies. The most common side effects are cataract and conjunctival haemorrhage.

The full indication is:

> Vabysmo is indicated for the treatment of adult patients with:
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> Neovascular (wet) age-related macular degeneration (nAMD),
>
> Visual impairment due to diabetic macular oedema (DME).

Vabysmo should be administered by a qualified physician 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.

[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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