EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/CHMP/656078/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Beovu

brolucizumab

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Beovu, intended for the treatment of neovascular (wet) age-related macular degeneration (AMD). The applicant for this medicinal product is Novartis Europharm Limited.

Beovu will be available as a 120 mg/ml solution for injection. The active substance of Beovu is brolucizumab, an anti-neovascularisation agent (ATC code: S01LA06), which inhibits vascular endothelial growth factor A, thereby suppressing endothelial cell proliferation, reducing pathological neovascularisation and decreasing vascular permeability.

The benefits with Beovu are its ability to preserve visual acuity, demonstrated over two years of treatment. The most common side effects are conjunctival haemorrhage and eye pain as well as intraocular inflammation and retinal artery occlusive events.

It is proposed that Beovu be prescribed by physicians experienced in administering intravitreal injections for the treatment of neovascular (wet) age-related macular degeneration (AMD).

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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