24 February 2022
EMA/CHMP/123447/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Beovu

brolucizumab

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Beovu. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted a new indication for visual impairment in diabetic macular oedema. The full indications for Beovu will therefore be as follows:[2]

> Beovu is indicated in adults for the treatment of
>
> - neovascular (wet) age related macular degeneration (AMD) (see section 5.1),
> - **visual impairment due to diabetic macular oedema (DME) (see section 5.1).**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in **bold**

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