21 March 2024
EMA/CHMP/101744/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lytenava

bevacizumab gamma

On 21 March 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lytenava, intended for treatment of neovascular (wet) age-related macular degeneration (nAMD).

The applicant for this medicinal product is Outlook Therapeutics Limited.

Lytenava will be available as 25 mg/ml solution for injection. The active substance of Lytenava is bevacizumab gamma, a humanised monoclonal antibody (ATC code: S01LA08) that binds to the vascular endothelial growth factor (VEGF) and prevents its activity.

The benefit of Lytenava is the preservation of vision in patients with wet AMD as measured in studies by best-corrected visual acuity. The most common side effects are conjunctival haemorrhage, eye pain, vitreous floaters and intraocular pressure increase.

The full indication is:

> Lytenava is indicated in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD).

Lytenava must be administered by qualified healthcare professional, 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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