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Biocon enters US ophthalmology market with US FDA approval of Yesafili

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Company has secured a launch date in Canada of no later than July 1, 2025



US Food and Drug Administration (US FDA) has approved Bengaluru-based Biocon Biologics' first-to-file application for Yesafili (aflibercept-jbvf), an interchangeable biosimilar aflibercept.

Yesafili, a vascular endothelial growth factor (VEGF) inhibitor used to treat several different types of ophthalmology conditions, is a biosimilar of its reference product EYLEA (aflibercept).

Yesafili is intended for the treatment of neovascular (wet AMD) age-related macular degeneration, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DME) and visual impairment due to myopic choroidal neovascularisation (myopic CNV). It is highly similar to the reference product Eylea (aflibercept). Data shows that Yesafili has comparable quality, safety, and efficacy to Eylea.

The approval marks Biocon Biologics' expansion into the ophthalmology therapeutic area in the United States following a steady track record of approval in Europe (September 2023) and the United Kingdom (November 2023) where it was the first biosimilar aflibercept to be approved. The company has secured a launch date in Canada of no later than July 1, 2025, under the terms of a settlement agreement.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics said: "The FDA approval of Yesafili (aflibercept) as the first interchangeable biological product to Eylea is a significant milestone for Biocon Biologics marking our entry into Ophthalmology, a new therapeutic area in the United States. Yesafili is approved for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy. This approval builds on our successful track record of bringing the first interchangeable insulin, SEMGLEE, the first biosimilar Trastuzumab, OGIVRI, and the first biosimilar Pegfilgrastim, FULPHILA, to patients in the United States."