

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Biocon Biologics Receives European Commission Approval for YESAFILI[®], Biosimilar Aflibercept

Bengaluru, Karnataka, India, September 20, 2023

Biocon Biologics Ltd., a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), has announced that the European Commission (EC) granted marketing authorization in the European Union (EU) for YESAFILI[®], a biosimilar of Aflibercept.

The EC decision follows the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) positive opinion recommending approval of YESAFILI[®] in July.

YESAFILI[®], an ophthalmology product, 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 centralized marketing authorization granted by the EC is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

Aflibercept had EU brand sales of approximately \$1.8B for the 12 months ending December 31, 2022, according to IQVIA.

“We are very pleased to receive the European Commission’s approval of our YESAFILI[®] biosimilar as we continue to expand our biosimilar offerings across the globe, building on our oncology and diabetes product portfolio. We look forward to making a meaningful difference to patients in the EU impacted by macular degeneration and diabetic retinopathy.” – Company Spokesperson

YESAFILI[®] is a registered trademark of a BBL company.

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