

Press Release

Biocon Biologics Announces Positive CHMP Opinion for YESAFILI[®], Biosimilar Aflibercept

BRIDGEWATER, New Jersey and BENGALURU, Karnataka, India, July 24, 2023

Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of YESAFILI[®], an aflibercept biosimilar.

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 CHMP positive opinion will be considered by the European Commission. The European Commission decision on the approval is expected by the end of September 2023.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said: "We are very pleased to receive a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for our YESAFILI[®] biosimilar. This is further confirmation of our strong commitment to providing high-quality and affordable medicines and represents another significant milestone as we continue to expand our biosimilar offerings across the globe, building on our robust presence in oncology and diabetes. We look forward to making a meaningful difference to patients in the EU impacted by macular degeneration and diabetic retinopathy through YESAFILI[®]."

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

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.

Aflibercept is a fusion protein consisting of portions of human VEGF (Vascular Endothelial Growth Factor) receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology.

YESAFILI® is registered trademark of a BBL company.

About Biocon Biologics Limited:

Biocon Biologics Ltd. (BBL), a subsidiary of Biocon Ltd., is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives by enabling affordable access to high quality biosimilars for millions of patients worldwide. It is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world- class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

BBL has acquired the global biosimilars business of its long-standing partner Viatrix, which is a historic milestone in its value creation journey. Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., EU, Australia, Canada, Japan.

The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, and other non-communicable diseases. It has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, BBL is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). Website: www.bioconbiologics.com; Follow us on Twitter: @BioconBiologics for company updates.

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development. Website: www.biocon.com; Follow-us on Twitter: @bioconlimited for company updates.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

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