Press Release

Biocon Biologics Obtains U.S. FDA Approval for Biosimilar Aflibercept for Yesafili™. Enters U.S. Ophthalmology Market

BRIDGEWATER, New Jersey *and* ***BENGALURU, Karnataka, India***: May 21, 2024:

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced that the U.S. Food and Drug Administration (US FDA) has approved the Company's 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 of YESAFILI 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 Ltd., 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."*

Matt Erick, Chief Commercial Officer of Advanced Markets, Biocon Biologics Ltd, *said: "Biosimilars are crucial for making healthcare more affordable and accessible. YESAFILI will offer ophthalmologists an important new option for patients impacted by macular degeneration and diabetic retinopathy,*

from a company with a long history of delivering high-quality, science-driven medicines, solely focused on the development and commercialization of biosimilars."

There are 19.8 million Americans living with age-related macular degeneration (AMD) in the United States.[1] In the U.S., sales of aflibercept were approximately $5.89 billion in 2023.[2]

Biocon Biologics is a leading global company offering a large portfolio of monoclonal antibodies, insulins, and conjugated proteins. It has achieved several "firsts" in the industry including the first to receive approval in the United States of a biosimilar trastuzumab (OGIVRI®, trastuzumab-dkst) and a biosimilar pegfilgrastim (FULPHILA®, pegfilgrastim-jmdb). Serving over 5.5M patients annually, Biocon Biologics has a comprehensive portfolio of in-market and in-development biosimilar products across multiple therapies, including four in the United States and six in Canada, with a robust pipeline of 20 biosimilar assets spanning multiple therapy areas.

[1] Rein DB, Wittenborn JS, Burke-Conte Z, Gulia R, Robalik T, Ehrlich JR, Lundeen EA, Flaxman AD. Prevalence of Age-Related Macular Degeneration in the United States in 2019. *JAMA Ophthalmology.* **Published Online:** November 3, 2022 at: https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2797921. Accessed April 29, 2024.
[2] Regeneron Fourth Quarter and Full Year 2023 Financial and Operating Results. February 2, 2024.

* An interchangeable product (IP) is a biological product that is approved based on data demonstrating that it is highly similar to an FDA-approved reference product (RP) and that there are no clinically meaningful differences between the products; it can be expected to produce the same clinical result as the RP in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between use of the RP and IP is not greater than that from the RP without such alternation or switch. Interchangeability of YESAFILI has been demonstrated for the condition(s) of use, strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

About YESAFILI:

The approval for YESAFILI (aflibercept-jbvf) was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that YESAFILI is highly similar to Eylea®. In a Phase 3 INSIGHT Study, YESAFILI was compared with Eylea® in patients with Diabetic Macular Edema. Study demonstrated that there were no clinically meaningful differences between YESAFILI and Eylea in terms of pharmacokinetics, safety, efficacy, and immunogenicity.

INDICATIONS AND USAGE:

YESAFILI is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

WARNINGS AND PRECAUTIONS:

- YESAFILI is contraindicated in patients with Ocular or periocular infection, Active intraocular inflammation and Hypersensitivity to aflibercept.
- Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion may occur following intravitreal injections. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

Please refer to full Prescribing Information for YESAFILI for more information. To report SUSPECTED ADVERSE REACTIONS, contact Biocon Biologics at 1-833-986-1468 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 integrated the acquired global biosimilars business of its long-standing partner Viatris, 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., Europe, Australia, Canada, and Japan. The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, 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 and LinkedIn: Biocon Biologics 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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