PRESS RELEASE

Biocon Biologics Secures Market Entry Date for Yesafili™, an Interchangeable Biosimilar to Eylea®, in the U.S.

BRIDGEWATER, New Jersey *and* ***BENGALURU, Karnataka, India***, April 15, 2025

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), announced today a settlement and license agreement with Regeneron that clears the way to commercialize Yesafili™ (aflibercept-jbvf), an interchangeable* biosimilar aflibercept, in the United States. YESAFILI, a vascular endothelial growth factor (VEGF) inhibitor, is used to treat several different types of ophthalmology conditions, is a biosimilar of its reference product EYLEA® (aflibercept).

Biocon Biologics and Regeneron executed the settlement agreement to dismiss the pending appeal at the United States Court of Appeals for the Federal Circuit (USCAFC) of patent US11084865 ('865 patent) and the pending litigation at the U.S. District Court for the Northern District of West Virginia, Clarksburg Division.

This agreement enables the Company to launch in the United States in the second half of calendar year 2026 or earlier in certain circumstances. The terms of the settlement are confidential.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd., said: *"This settlement clears the path for Biocon Biologics to be among the first to bring a reliable, high-quality aflibercept biosimilar to patients and healthcare providers in the United States. As the first-to-file interchangeable biosimilar to Eylea®, YESAFILI affirms our scientific strength and marks our strategic entry into Ophthalmology, expanding our footprint in the U.S. and advancing our mission to increase access to life-changing treatments."*

Previously, the U.S. Food and Drug Administration (U.S. FDA) approved Yesafili™ (aflibercept-jbvf), an interchangeable* biosimilar aflibercept in May 2024. Additionally, Biocon Biologics secured a settlement agreement in Canada with Bayer Inc. and Regeneron Pharmaceuticals, Inc., for the launch of YESAFILI™ no later than July 1, 2025.

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®.

*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 Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve millions of patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company 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.

Biocon Biologics has commercialized nine biosimilars from its pipeline of 20 products in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. Its pipeline has several biosimilar assets under development across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases. The Company has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it 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 **X** *(formerly 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 **X** *(formerly Twitter)* @bioconlimited and **LinkedIn**: Biocon 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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