

PRESS RELEASE

Biocon Biologics Receives Health Canada Approval for Yesafili™ (aflibercept); First Global Launch Scheduled for July 2025

TORONTO, Ontario, Canada and BENGALURU, Karnataka, India: June 27, 2025

Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), is pleased to announce that Health Canada has granted a Notice of Compliance (NOC) for Yesafili™ (aflibercept), a biosimilar to Eylea® (aflibercept) injection, in vial and prefilled syringe presentations, 2 mg/0.05 mL on June 26, 2025. This approval paves the way for the launch of YESAFILI in Canada, scheduled for July 4, 2025. YESAFILI is the first biosimilar to EYLEA to be approved by Health Canada.

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

- Neovascular (wet) age-related macular degeneration (AMD)
- Visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO)
- Visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO)
- Diabetic macular edema (DME)
- Myopic choroidal neovascularization (myopic CNV)

The approval is based on a comprehensive package of analytical, nonclinical, and clinical data, confirming that YESAFILI is highly similar with no clinically meaningful differences to EYLEA in terms of quality, safety, and efficacy.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd., said: “The approval of YESAFILI by Health Canada—the first biosimilar to EYLEA® in Canada—is a proud moment for Biocon Biologics. We are excited that in July, Canada will be the first country where we will launch YESAFILI, making it our 10th biosimilar to be commercialized worldwide. This milestone reflects our science-driven innovation, global commercialization strength, and continued commitment to expanding access to high-quality, affordable biologics for patients across the globe.”

Ramy Ayad, Head of Canada at Biocon Biologics, stated: “This is a significant achievement for Biocon Biologics in Canada. With the approval of YESAFILI, we are delivering on our promise to improve access to advanced biologic therapies. Canadian ophthalmologists and patients will soon have a high-quality, affordable biosimilar option for serious retinal diseases.”

About YESAFILI™:

The approval for YESAFILI (aflibercept) 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. This study demonstrated that there were no clinically meaningful differences between YESAFILI and EYLEA in terms of pharmacokinetics, safety, efficacy, and immunogenicity.

Indications and Usage:

Treatment with YESAFILI (aflibercept) is for intravitreal injection only.

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

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO)
- Visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO)
- Diabetic Macular Edema (DME)
- Myopic choroidal neovascularization (myopic CNV)

Warnings and Precautions:

- YESAFILI is contraindicated in patients with ocular or periocular infection, active intraocular inflammation, and hypersensitivity to aflibercept, to any ingredient in the formulation or to any component of the container.
- Patients may experience temporary visual disturbances after an intravitreal injection with YESAFILI and the associated eye examinations. They should not drive or use machines until visual function has recovered sufficiently.
- Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intraocular inflammation.
- Endophthalmitis, retinal detachment, retinal tear, retinal pigment epithelium tear, cataract including traumatic cataract, vitreous hemorrhage and hyphema, may occur following intravitreal injections.
- Retinal vasculitis and retinal occlusive vasculitis, typically in the presence of intraocular inflammation or treatment with other intravitreal agents.
- Increases in intraocular pressure have been observed within 60 minutes of an intravitreal injection

Please refer to full Product Monograph for YESAFILI for more information.

To report SUSPECTED ADVERSE REACTIONS, contact Biocon Biologics at 1-833-986-1468.

YESAFILI is a trademark of a Biocon Biologics Company.

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All other trademarks are the property of their respective owners.

About Biocon Biologics Limited:

Biocon Biologics Limited, 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 over 5.8 million 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 portfolio which are addressing the patients' needs in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, bone health 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. For FY24 Integrated Annual Report of Biocon Biologics [click here](#)

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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