

Biocon Announces Publication of Pivotal Clinical Data Supporting Effectiveness of Yesafili™, a Biosimilar to Eylea® (Aflibercept)

- **Key findings published in the *British Journal of Ophthalmology*:** Patients who continued on MYL-1701P and those who switched from reference aflibercept to MYL-1701P showed **similar safety, efficacy, and immunogenicity outcomes through the 20-week extension**, with maintained visual and anatomic results.
- **Key findings published in *Expert Opinion on Biological Therapy*:** Across clinically relevant patient subgroups, MYL-1701P demonstrated **comparable improvements in visual acuity and retinal thickness to reference aflibercept**, supporting clinical equivalence across diverse DME populations.

BENGALURU, India and BRIDGEWATER, N.J., United States: July 9, 2026

Biocon Limited (BSE: 532523; NSE: BIOCON), an innovation-led global biopharmaceutical company, today announced the publication of two important clinical studies supporting the effectiveness of **Yesafili™ (aflibercept-jbvf)**. The clinical data from the Phase III INSIGHT program evaluating MYL-1701P, its aflibercept biosimilar, was published in two peer-reviewed journals, contributing to the clinical evidence base supporting the development of aflibercept MYL-1701P for the treatment of diabetic macular edema (DME). MYL-1701P was approved and the vial format was granted **interchangeable designation** under the name Yesafili™ by the U.S. Food and Drug Administration in [May 2024](#).

Shreehas Tambe, CEO & Managing Director, Biocon, said, “*Findings from these peer-reviewed publications represent an important milestone for our aflibercept biosimilar program as we prepare for our upcoming launch in the United States. Together, these studies demonstrate how our science-led approach continues to expand access to biosimilars for patients.*”

Safety and Efficacy of Biosimilar Aflibercept MYL-1701P in Diabetic Macular Oedema: 20-Week Extension Results Following the INSIGHT Pivotal Trial

The first manuscript, titled “**Safety and Efficacy of Biosimilar Aflibercept MYL-1701P in Diabetic Macular Oedema: 20-Week Extension Results Following the INSIGHT Pivotal Trial**,” was published in the *British Journal of Ophthalmology* on June 29, 2026.

This publication reports results from a 20-week, multicenter, open-label extension study enrolling participants with Diabetic Macular Edema (DME) who completed the 52-week global Phase III INSIGHT trial. The study evaluated the safety, efficacy and immunogenicity of MYL-1701P in participants who either continued treatment with MYL-1701P or switched from reference aflibercept to MYL-1701P.

The results demonstrated comparable safety, efficacy, and immunogenicity profiles between participants who continued on MYL-1701P and those who switched from reference aflibercept. Safety was assessed by the incidence of ocular and non-ocular treatment-emergent adverse events, while efficacy outcomes included best corrected visual acuity, central subfield thickness and participants who gained ETDRS (Early Treatment Diabetic Retinopathy Study) letters. The findings demonstrate that

functional and anatomic outcomes were maintained through the extension period in both treatment groups.

Comparability of Aflibercept Biosimilar with Reference Aflibercept in Diabetic Macular Edema: Subgroup Analysis of the Pivotal Phase-III INSIGHT Randomized Clinical Trial

The second manuscript, titled “[Comparability of Aflibercept Biosimilar with Reference Aflibercept in Diabetic Macular Edema: Subgroup Analysis of the Pivotal Phase-III INSIGHT Randomized Clinical Trial](#),” was published on May 18, 2026 in *Expert Opinion on Biological Therapy*.

This publication presents exploratory subgroup analyses from the Phase III INSIGHT randomized clinical trial comparing MYL-1701P with reference aflibercept in participants with DME. Subgroups were defined based on baseline characteristics including visual acuity, central subfield thickness, age, gender, race, ethnicity, geographic region, glycosylated hemoglobin, anti-drug antibody status, and prior anti-VEGF therapy in the fellow eye.

The subgroup analyses showed clinically comparable changes in best corrected visual acuity and central subfield thickness between MYL-1701P and reference aflibercept across most subgroups at both early and later timepoints. The findings support clinical equivalence between the aflibercept biosimilar and reference product within the evaluated subgroups.

Dr. Elena Wolff-Holz, Chief Medical Officer, Biocon, said, “*The data from these publications reinforce the clinical evidence generated through the Phase III INSIGHT trial, demonstrating consistency of outcomes following a switch from reference aflibercept and comparability across clinically relevant patient subgroups. This adds to the growing body of evidence supporting MYL-1701P as a reliable treatment option for diabetic macular edema.*”

Epidemiology:

There are 19.8 million Americans living with age-related macular degeneration (AMD) in the United States.¹ Macular degeneration, specifically age-related macular degeneration (AMD), is a significant health concern, especially as the population ages. It is a leading cause of irreversible vision loss in adults over 60². In 2019, an estimated 12.6% of Americans age 40 and older were living with AMD, with 1.49 million (0.94%) living with vision threatening.³

About YESAFILI (aflibercept-jbvf)

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 III INSIGHT Study, YESAFILI was compared with EYLEA in patients with Diabetic Macular Edema. The 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)

¹ [Prevalence of Age-Related Macular Degeneration in the US in 2019 | Geriatrics | JAMA Ophthalmology | JAMA Network](#)

² [Macular Degeneration: Symptoms, Diagnosis & Treatment](#)

³ [VEHSS Modeled Estimates: Age-Related Macular Degeneration \(AMD\) | Vision and Eye Health Surveillance System \(VEHSS\) | CDC](#)

- 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 the full Patient Information for detailed safety information. To report SUSPECTED ADVERSE REACTIONS, contact Biocon at 1-833-986-1468.

About Biocon Limited

Biocon Limited (BSE: 532523, NSE: BIOCON) is a global biopharmaceutical company driven by its purpose to provide affordable, life-changing medicines to patients worldwide. Headquartered in Bengaluru, India, Biocon addresses some of the world's most pressing healthcare challenges across chronic and non-communicable diseases by offering both biosimilars and generics at scale across geographies. Through this diversified portfolio, Biocon focuses on areas of high unmet need, spanning key therapy areas including diabetes, oncology, obesity, cardiovascular diseases, immunology, ophthalmology, and bone health. The Company has pioneered several industry firsts that have helped shape the global biosimilars landscape. To date, the company has commercialized 12 biosimilar products and 30+ generic formulations globally. It has robust research and development pipeline of 20+ biosimilar assets, as well as GLP-1 peptides and other complex generics. With an integrated lab-to-patient model, Biocon brings together research and development, manufacturing, and commercial capabilities to ensure reliable and scalable supply of medicines. The company operates in more than 120 countries, supported by seven manufacturing sites, three R&D sites, 18 offices worldwide, and a workforce of over 9,500 employees. Biocon has been included in the S&P Global Sustainability Yearbook 2026 for the fourth consecutive year, underscoring its commitment to sustainable and responsible growth. Website: www.biocon.com Follow us on X: [@bioconlimited](https://twitter.com/bioconlimited) LinkedIn: [Biocon](https://www.linkedin.com/company/biocon)

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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