

Press Release

Biocon Biologics Announces Results of Aflibercept Switching Study at American Academy of Ophthalmology Annual Meeting

BRIDGEWATER, N.J., United States and BENGALURU, Karnataka, India: October 23, 2024

Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), announced a new extension study evaluating MYL-1701P, a proposed biosimilar to aflibercept. MYL-1701P showed promising results, demonstrating comparable safety, efficacy, and immunogenicity between patients continuing on MYL-1701P and those who switched from aflibercept to MYL-1701P. The data were presented at the annual meeting of the American Academy of Ophthalmology.

This extension of the pivotal Phase III study aimed to further assess the safety and efficacy of MYL-1701P in two groups: patients who continued the original treatment assignment of MYL-1701P (the continuation arm) and those who switched from reference aflibercept to MYL-1701P (the switch arm). Both groups received three doses of MYL-1701P (2 mg intravitreal injections) at weeks 56, 64, and 72.

The primary endpoint of the study was the incidence of treatment-emergent adverse events (TEAEs). Of the 52 participants, 46 (88.5%) completed the study through week 76. The results demonstrated that TEAEs occurred in 9 out of 29 participants (31%) in the continuation arm and in 7 out of 23 participants (30%) in the switch arm, showing no significant difference between the two groups.

Additionally, no treatment-induced or boosted anti-drug antibodies were detected in any of the participants, further supporting the safety profile of MYL-1701P. The adjusted mean difference in change in Best Corrected Visual Acuity (BCVA) between baseline and week 76 (switch minus continuation arm) was -1.20 Early Treatment Diabetic Retinopathy Study (ETDRS) letters, with a 90% confidence interval of -6.15 to 3.75 ETDRS letters, indicating that the two groups had similar outcomes in terms of visual acuity improvement.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, *“The results of this study are an important step forward in expanding treatment options for patients and giving ophthalmologists informative evidence to guide their clinical practice. MYL-1701P offers the potential for widely increasing access to an important treatment for many patients suffering from eyesight threatening conditions.”*

The results were presented at the annual meeting of the American Academy of Ophthalmology:

Poster Title: Randomized Trial of MYL-1701P (Proposed Aflibercept Biosimilar) vs Aflibercept through 76 Weeks in DME including Switch from Aflibercept

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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 eight biosimilars in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 12 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](https://twitter.com/BioconBiologics) and **LinkedIn**: [Biocon Biologics](https://www.linkedin.com/company/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.

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