

PRESS RELEASE

Biocon Biologics Announces Positive Results from Phase 3 Study of Yesintek™ Biosimilar to Ustekinumab for Chronic Plaque Psoriasis

BRIDGEWATER, N.J., United States and BENGALURU, Karnataka, India: March 7, 2025 -- Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced the successful results of a pivotal Phase 3, randomized, double-blind, parallel group, multicenter study comparing Yesintek™ (Biocon Biologics' biosimilar to Ustekinumab, called YESINTEK) with reference product Stelara (Ustekinumab) in adult patients with moderate to severe chronic plaque psoriasis (PsO). The data are being presented at the 2025 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida.

The study demonstrated equivalent efficacy, safety, immunogenicity, and pharmacokinetics between YESINTEK and the reference product Stelara (Ustekinumab), marking a significant milestone for Biocon Biologics in advancing the accessibility of biosimilar therapies for patients worldwide.

Elena Wolff-Holz, M.D., Global Head Clinical Development, Biocon Biologics said, "The positive results from this Phase 3 study reaffirm the quality and therapeutic equivalence of YESINTEK compared to reference product Ustekinumab. This milestone underscores our commitment to providing cost-effective, high-quality biosimilars to patients with chronic conditions like psoriasis, expanding access to critical treatments globally."

The primary efficacy endpoint, percentage change from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12, demonstrated that YESINTEK was equivalent to reference Stelara (Ustekinumab), with both treatments showing similar improvement in PASI scores. The mean difference between the two groups was 0.68%, falling within the predefined equivalence margins for both the U.S. Food and Drug Administration (U.S. FDA) and European Medicines Agency (EMA).

The safety profile of YESINTEK was similar to the reference product Stelara (Ustekinumab) through the duration of the study.

The pharmacokinetic and immunogenicity profiles of YESINTEK were found to be similar to those of reference Stelara (Ustekinumab), with no significant differences in efficacy or safety outcomes between the two treatments. Additionally, the study assessed the impact of switching from reference Stelara (Ustekinumab) to YESINTEK at Week 16, with results showing continued efficacy and safety through Week 52.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "The results from this study show convincingly once more that in-vitro analytical comparability translates well into in-vivo clinical performance. The study reinforces the confidence we can have in the biosimilar regulatory pathways and the principles they are built on. Specifically, for YESINTEK the study shows that it offers an effective, safe, and comparable alternative to reference Ustekinumab in the treatment of moderate

to severe chronic plaque psoriasis and by extension the other indications for which Ustekinumab is indicated. YESINTEK is another important addition to our portfolio of affordable biologics that promise improved patient care by providing a cost-effective treatment option without compromising clinical outcomes.”

The study is being presented as:

Poster Title: Randomized, double-blind, parallel group, multicenter, Phase 3 study to demonstrate equivalent efficacy and to assess safety, immunogenicity and pharmacokinetics of BMAb-1200 compared to reference Ustekinumab in adult subjects with moderate to severe chronic plaque psoriasis

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Category: Psoriasis & Other Papulosquamous Disorders

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About YESINTEK

YESINTEK is a biosimilar medicine to Ustekinumab, a monoclonal antibody that targets interleukins IL-12 and IL-23, which play a key role in the immune-mediated pathogenesis of psoriasis and other autoimmune diseases. The Phase 3 study enrolled 384 adult patients aged 18-80 years who had a confirmed diagnosis of moderate to severe chronic plaque psoriasis. The primary objective was to demonstrate the equivalent efficacy of YESINTEK and reference Stelara (Ustekinumab), while assessing secondary outcomes related to safety, tolerability, immunogenicity, and pharmacokinetics. Additionally, the study assessed the impact of switching from reference Stelara (Ustekinumab) to YESINTEK. The [U.S. FDA approved YESINTEK](#) in December 2024.

YESINTEK has been approved by the US FDA for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn’s disease and moderately to severely active ulcerative colitis. Additionally, it has been approved for pediatric patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy and active psoriatic arthritis.

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. It’s 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](https://twitter.com/bioconlimited) and **LinkedIn:** [Biocon](https://www.linkedin.com/company/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.

YESINTEK is a registered trademark of Biocon Biologics Limited

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