PRESS RELEASE

Biocon Biologics Launches Yesintek™ (ustekinumab-kfce) Biosimilar to Stelara® in the United States

BRIDGEWATER, N.J., United States and BENGALURU, Karnataka, India: **February 24, 2025 -- Biocon Biologics Ltd. (BBL)**, a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced that YESINTEK™ (ustekinumab-kfce) is now available to patients in the United States, and is one of the first Stelara® (ustekinumab) biosimilar market entrants in the country.

YESINTEK is approved for the treatment of Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis, increasing patient access to more cost-effective treatment options for use in the treatment of common chronic autoimmune diseases. YESINTEK will be available in all the same formulations currently provided by Stelara. The available presentations are 45 mg/0.5 mL PFS, 90 mg/mL PFS, 45 mg/0.5 mL vial, and 130 mg/26 mL vial.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said: *"The launch of YESINTEK marks a significant step in our commitment to improving the lives of patients with inflammatory conditions and expanding access to high-quality biosimilars. It also represents our first product launch in the United States since becoming a fully integrated global biosimilars organization. We are excited to be among the first companies to introduce a high-quality, affordable biosimilar Ustekinumab to this patient population."*

Laura Wingate, Chief Education, Support & Advocacy Officer of the Crohn's & Colitis Foundation, said: *"The burden of Crohn's disease and ulcerative colitis on patients' daily lives is substantial. This is a meaningful advancement for eligible chronic disease patients, who now have more treatment options available."*

YESINTEK will have commercial payor coverage at launch and also have a robust patient assistance program that includes benefits verification, copay support, among other services. The copay program is competitive with the originator offering and eligible patients that meet the program criteria may pay as little as $0.

YESINTEK is a monoclonal antibody that disrupts IL-12 and IL-23 mediated signaling associated immune mediated diseases. Clinical studies showed that YESINTEK is a biosimilar to Stelara® and has similar pharmacokinetic, safety, efficacy and immunogenicity profile compared with Stelara®. YESINTEK received U.S. Food and Drug Administration (FDA) approval in December 2024.

Josh Salsi, Head of North America, Biocon Biologics Inc., said: *"For healthcare providers, switching to YESINTEK offers a seamless treatment experience covering the same indications and dosing options. Patients can feel confident that YESINTEK comes from Biocon Biologics, a company with extensive biosimilar expertise in immunology."*

For more information and resources, please visit www.yesintek.com. Health care professionals can access more information at www.yesintekHCP.com.

About YESINTEK
The approval for YESINTEK (ustekinumab-kfce) was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that YESINTEK is highly similar to Stelara®. In a Phase 3 STELLAR-2 Study, YESINTEK was compared with Stelara® in patients with moderate-to-severe chronic Plaque Psoriasis. The study demonstrated that there were no clinically meaningful differences between YESINTEK and Stelara in terms of pharmacokinetics, safety, efficacy, and immunogenicity.

INDICATIONS AND USAGE:
YESINTEK is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's Disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:
- Moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

CONTRAINDICATIONS
Clinically significant hypersensitivity to ustekinumab or to any of the excipients in YESINTEK.

WARNINGS AND PRECAUTIONS:
- Infections: Serious infections have occurred. Avoid starting YESINTEK during any clinically important active infection. If a serious infection or clinically significant infection develops, discontinue YESINTEK until the infection resolves.
- Theoretical Risk for Particular Infections: Serious infections from mycobacteria, salmonella and Bacillus Calmette-Guerin (BCG) vaccinations have been reported in patients genetically deficient in IL-12/IL-23. Consider diagnostic tests for these infections as dictated by clinical circumstances.
- Tuberculosis (TB): Evaluate patients for TB prior to initiating treatment with YESINTEK. Initiate treatment of latent TB before administering YESINTEK.
- Malignancies: Ustekinumab may increase risk of malignancy. The safety of ustekinumab products in patients with a history of or a known malignancy has not been evaluated.
- Hypersensitivity Reactions: If an anaphylactic or other clinically significant hypersensitivity reactions occurs, institute appropriate therapy and discontinue YESINTEK.
- Posterior Reversible Encephalopathy Syndrome (PRES): If PRES is suspected, treat promptly and discontinue YESINTEK.
- Immunizations: Avoid use of live vaccines in patients during treatment with YESINTEK.

- Noninfectious Pneumonia: Cases of interstitial pneumonia, eosinophilic pneumonia and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. If diagnosis is confirmed, discontinue YESINTEK and institute appropriate treatment.

Please refer to full Prescribing Information for YESINTEK 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 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 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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