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BIO/SECL/TG/2025-26/107

October 23, 2025

To The Manager, **BSE Limited** Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, **National Stock Exchange of India Limited** Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code - 532523	**Scrip Symbol - BIOCON**

Dear Sir/ Madam,

Subject: Press Release

Please find enclosed the press release titled "**Biocon Biologics Receives Health Canada Approval for Yesintek™ and Yesintek™ I.V. (ustekinumab), a Biosimilar to Stelara®**".

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

RAJESH U SHANOY
Digitally signed by RAJESH U SHANOY
Date: 2025.10.23 08:08:27 +05'30'

Rajesh U. Shanoy
Company Secretary and Compliance Officer
M. No.: ACS 16328

Encl: Press Release

PRESS RELEASE

Biocon Biologics Receives Health Canada Approval for Yesintek™ and Yesintek™ I.V. (ustekinumab), a Biosimilar to Stelara®

***TORONTO, Ontario, Canada and BENGALURU, Karnataka, India*: October 23, 2025**

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE: 532523, NSE: BIOCON), today announced that Health Canada has granted a Notice of Compliance (NOC) for Yesintek™ (ustekinumab injection) and Yesintek™ I.V. (ustekinumab for injection, solution for intravenous infusion), a biosimilar to Stelara® (ustekinumab injection) and Stelara® I.V. (ustekinumab for injection, solution for intravenous infusion). The approval was granted on October 17, paving the way for Canadian commercial availability in mid-October.

YESINTEK and YESINTEK I.V. are indicated for the treatment of moderate to severe plaque psoriasis in adult patients and in pediatric patients (6-17 years of age), active psoriatic arthritis in adults, moderately to severely active Crohn's disease and ulcerative colitis in adults—a range of debilitating autoimmune conditions that affect thousands of Canadians.

Health Canada approval was based on a comprehensive data package, confirming that YESINTEK is highly similar to Stelara with no clinically meaningful differences in efficacy, safety and immunogenicity. YESINTEK will be available through the **My Biocon Biologics™** patient support program, which provides assistance to individuals prescribed with the therapy. YESINTEK is available as a subcutaneous injection, 45 mg/0.5ml (prefilled syringe and vial) and 90 mg/ml (prefilled syringe) and YESINTEK I.V. as an intravenous solution, 130 mg/26mL (5mg/mL).

***Shreehas Tambe, CEO & Managing Director, Biocon Biologics**, said:* "Health Canada's approval of Yesintek™ marks a significant milestone in our mission to expand global access to high-quality biosimilars. Building on our successful U.S. launch, this approval strengthens our presence in North America and enhances our immunology portfolio with a more affordable treatment option for Canadian patients living with chronic autoimmune conditions."

***Ramy Ayad, Head of Canada at Biocon Biologics**, said:* "We are excited to bring Yesintek™ to Canadian patients, providing a trusted, value-driven ustekinumab biosimilar. Biocon Biologics is committed to advancing biosimilar adoption in Canada to improve outcomes for patients and deliver meaningful savings to the healthcare ecosystem. By expanding access in both public and private markets, we aim to help build a sustainable biosimilars industry that benefits all Canadians."

About YESINTEK:

YESINTEK (ustekinumab injection) and YESINTEK I.V. (ustekinumab for injection, solution for intravenous infusion) is a biosimilar to STELARA and STELARA I.V., a fully human IgG1κ monoclonal

antibody, a first-in-class agent that binds with specificity to the shared p40 protein subunit of human cytokines interleukin IL-12 and IL-23 mediated signaling associated with immune-mediated diseases. The Phase 3 STELLAR-2 study demonstrated no clinically meaningful differences between YESINTEK and STELARA in terms of pharmacokinetics, efficacy, safety, and immunogenicity.

Important Safety Information

Contraindications:

- Hypersensitivity to YESINTEK/YESINTEK I.V. or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Severe infections such as sepsis, tuberculosis, and opportunistic infections.

Warnings and Precautions:

- Infections: Ustekinumab is a selective immunomodulator and may have the potential to increase the risk of infections and reactivate latent infections. Patients should be evaluated for tuberculosis prior to initiating treatment. Do not give YESINTEK to patients with any clinically important active infection. Monitor for signs and symptoms of infection during and after treatment.
- Malignancy: Ustekinumab has the potential to increase the risk of malignancy. Use caution in patients with a history of malignancy or if malignancy develops. Monitor for skin cancer, particularly patients >60 years of age, those with prolonged immunosuppressant therapy, or prior PUVA treatment.
- Concomitant Immunosuppressive Therapy: Caution should be exercised when considering concomitant use of immunosuppressive agents with YESINTEK or when transitioning from other biologics.
- Immunization: live viral or bacterial vaccines should not be given concurrently. Patients may receive inactivated or non-live vaccines; however, non-live vaccines during therapy may not elicit a sufficient response.
- For infants exposed in utero, a six-month waiting period is recommended before administration of live vaccines (earlier may be considered if infant serum ustekinumab is undetectable or if benefits outweigh risks).
- Allergy Immunotherapy: Ustekinumab has not been evaluated in patients who have undergone allergy immunotherapy. Ustekinumab may affect allergy immunotherapy. Caution should be exercised in patients receiving or who have received allergy immunotherapy, particularly for anaphylaxis.
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS): A serious neurological disorder that can present with headache, seizures, confusion, and visual disturbances. Conditions with which it has been associated include preeclampsia, acute hypertension, cytotoxic agents, immunosuppressive therapy, and alcohol abuse. Fatal outcomes have been reported.
- Hypersensitivity Reactions: Serious allergic reactions, including anaphylaxis and angioedema, have been reported. Rare cases of allergic alveolitis and eosinophilic pneumonia have also occurred; some cases led to respiratory failure and prolonged hospitalization.

- Women of Childbearing Potential: Women should use effective contraception during treatment and for at least 15 weeks after the last dose and receive preconception counselling before planning a pregnancy.

Refer to the full Canadian Product Monograph for detailed safety information.
To report SUSPECTED ADVERSE REACTIONS, contact Biocon Biologics at 1-833-986-1468.

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 6.0 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 10 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). The meaningful progress on ESG parameters has been recognized with the Company's inclusion in the S&P Global Sustainability Yearbook in 2025. 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.

For More Information: Biocon Biologics	
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