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BIO/SECL/TG/2025-26/60

July 15, 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 Expands Diabetes Portfolio with FDA Approval of Kirsty™, the First and Only Interchangeable Rapid-Acting Insulin Aspart in the United States**".

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**

EKTA AGARWAL
Digitally signed by EKTA AGARWAL
Date: 2025.07.15 23:52:35 +05'30'

Ekta Agarwal
Interim Company Secretary and Compliance Officer
Membership No.: FCS 11388
Encl: Press Release

PRESS RELEASE

Biocon Biologics Expands Diabetes Portfolio with FDA Approval of Kirsty™, the First and Only Interchangeable Rapid-Acting Insulin Aspart in the United States

BRIDGEWATER, N.J., United States and BENGALURU, Karnataka, India: **July 15, 2025**

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced that the U.S. Food and Drug Administration (FDA) has approved Kirsty™ (Insulin Aspart-xjhz), 100 units/mL as the first and only interchangeable* biosimilar to NovoLog® (Insulin Aspart). KIRSTY is a rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. KIRSTY will be available as a single-patient-use prefilled pen for subcutaneous use and a multiple-dose vial for subcutaneous and intravenous use.

The FDA approval of KIRSTY expands Biocon Biologics' biosimilar insulin portfolio, which also includes the first approved interchangeable biosimilar, Semglee® (Insulin Glargine-yfgn Injection). KIRSTY has been available in Europe and Canada since 2022.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd.*, said:* "The FDA approval of Kirsty™, the first and only interchangeable biosimilar rapid-acting Insulin Aspart in the U.S., is a significant step forward in our efforts to make insulin more accessible and affordable. It builds on the foundation we laid with Semglee®, reinforcing our commitment to scientific excellence and patient-centric innovation. With Kirsty™, we are expanding treatment choices for people living with diabetes and advancing our ambition to be a global leader in addressing unmet needs in diabetes care."

There are 38.4 million people with diabetes in the United States, approximately 11.6 percent of the total population, with nearly a quarter of them being undiagnosed. An additional 97.6 million Americans have been identified as prediabetic.[1] Sales of Insulin Aspart in the United States were approximately $1.9 billion in 2024, according to IQVIA.

Biocon Biologics is a global leader in biosimilars and insulin production and is among the top three global players for rh- Insulin and Insulin Glargine, providing over 9.2 billion doses of insulin globally with a broad portfolio comprising basal, mixed and rapid acting insulins.

The Company has achieved many "firsts" in the industry including the first to receive approval of biosimilar Trastuzumab in the United States, Ogivri®, as well as Fulphila™ (bPegfilgrastim), and Semglee® (bInsulin Glargine) in the United States. Globally, serving over 5.8M patients annually, Biocon Biologics has a comprehensive portfolio of in-market and in-development biosimilar products across multiple therapies, including eight in the United States and seven in Canada, with a robust portfolio of 20 biosimilar assets, including insulins and monoclonal antibodies spanning multiple therapy areas.

* An interchangeable product (IP) is a biological product that is approved based on data demonstrating that it is highly similar to an FDA-approved reference product (RP) and that there are no clinically meaningful differences between the products; it can be expected to produce the same clinical result as the RP in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between use of the RP and IP is not greater than that from the RP without such alternation or switch. Interchangeability of KIRSTY has been demonstrated for the condition(s) of use, strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

About KIRSTY:

The approval for KIRSTY was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that KIRSTY is highly similar to NOVOLOG. The data demonstrated that there were no clinically meaningful differences between KIRSTY and NOVOLOG in terms of safety, efficacy, purity and potency.

Important safety information:

KIRSTY is contraindicated

- During episodes of hypoglycemia and patients with hypersensitivity to insulin aspart products or any of the excipients in KIRSTY.

Warnings and Precautions:

- Never share a KIRSTY prefilled pen, needles or syringes between patients, even if the needle is changed.
- Hyperglycemia or hypoglycemia with changes in insulin regimen: changes to a patient's insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) should be under close medical supervision with increased frequency of blood glucose monitoring.
- Hypoglycemia: May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, concomitantly administered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairments and hypoglycemia unawareness.
- Medication Errors: Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection
- Hypersensitivity reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, may occur. Discontinue KIRSTY, treat, and monitor if indicated.
- Hypokalemia: May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated.
- Fluid retention and heart failure with concomitant use of thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.
- Hyperglycemia and Ketoacidosis Due to Insulin Pump Device
- Malfunction: Monitor glucose and administer KIRSTY by subcutaneous injection if pump malfunction occurs.

Please refer to full Prescribing Information for KIRSTY (Insulin Aspart-xjhz injection) for more information.

[1] U.S. Department of Health & Human Services, Centers for Disease Control and Prevention. "National Diabetes Statistics Report." Accessed: January 28, 2025. Last Reviewed: May 15, 2024. https://www.cdc.gov/diabetes/php/data-research/index.html

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 5.8 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 nine 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). **Website**: www.bioconbiologics.com; **Follow us on X** *(formerly Twitter)*: @BioconBiologics and **LinkedIn**: Biocon Biologics for company updates. For FY24 Integrated Annual Report of Biocon Biologics click here

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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