PRESS RELEASE

Biocon Biologics and Civica Expand Partnership and Launch Private-Label Insulin Glargine to Broaden U.S. Diabetes Treatment Options

Additional treatment options for the 38.4 million U.S. patients living with diabetes

BRIDGEWATER, N.J. and BENGALURU, Karnataka, India: **October 16, 2025**

Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced expansion of its strategic collaboration with **Civica, Inc. (Civica)** to include a new Insulin Glargine medicine that will benefit patients in the United States by increasing supply of high-quality affordable insulins.

The multi-year transformational agreement between Biocon Biologics and Civica creates an exclusive distributorship arrangement where Biocon Biologics will manufacture and supply Insulin Glargine medicine to Civica, and Civica will commercialize under Biocon Biologics' existing marketing approval (a private label agreement). Civica will distribute, promote, and sell the medicine in the United States under a separate Civica label and trade dress, and in California, the product will carry the CalRx brand. Biocon Biologics will continue to directly commercialize Biocon Biologics' own Insulin Glargine-yfgn medicine, which was approved by the U.S. Food and Drug Administration (FDA) in July 2021 as the first interchangeable biosimilar.

***Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said**: "Biocon Biologics is committed to expanding access to affordable, high-quality insulins in the U.S. and globally. By extending our collaboration with Civica, Inc. to include Insulin Glargine, we are building on our differentiated approach to serving and enhancing patient access—by retaining our direct commercialization and through this strategic partnership. This collaboration enables us to reach underserved populations through new channels in direct alignment with our mission."*

No technology transfer is involved in the agreement and Biocon Biologics will continue to own the intellectual property and marketing authorization associated with Insulin Glargine. Additional terms of the agreement are not disclosed.

This agreement expands the relationship between the two organizations that previously announced that Biocon Biologics will provide Civica with [Insulin Aspart drug substance to manufacture in the United States].

***Ned McCoy, President and Chief Executive Officer, Civica, Inc.,** said:* "We are pleased to expand our partnership with Biocon Biologics, which helps us achieve a significant milestone in our insulin initiative. Today's announcement allows us to realize our goal of bringing insulin to people who need it at a transparent low price."

Insulin glargine-yfgn injection is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of use: Insulin glargine-yfgn is not recommended for the treatment of diabetic ketoacidosis.

There are 38.4 million people with diabetes in the United States, approximately 11.6 percent of the total population, with nearly a quarter being undiagnosed. An additional 97.6 million Americans have been identified as prediabetic.[1]

Biocon Biologics is a global leader in biosimilars and insulin production and is the fourth largest insulins company in the world, providing over 9.2 billion doses of insulin globally with a broad portfolio comprising basal, mixed and rapid acting insulins.

Important Safety Information:

Insulin Glargine-yfgn is contraindicated

- during episodes of hypoglycemia and in patients with hypersensitivity to insulin glargine products or any of the excipients in Insulin Glargine-yfgn.

Warnings and Precautions:

- Insulin pens, needles, or syringes must never be shared between patients. Do NOT reuse needles.
- Monitor blood glucose in all patients treated with insulin. Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring.
- Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia. Advise patients to rotate the injection site to unaffected areas and closely monitor for hypoglycemia.
- Hypoglycemia is the most common adverse reaction associated with insulins, including insulin glargine products. Severe hypoglycemia can cause seizures, may be life threatening, or cause death. Hypoglycemia can impair concentration and reaction time.
- Accidental mix-ups between insulin products have been reported. To avoid medication errors between Insulin Glargine-yfgn and other insulins, instruct patients to always check the insulin label before each injection.
- Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue Insulin Glargine-yfgn, treat and monitor until symptoms and signs resolve.
- All insulin products, including Insulin Glargine-yfgn, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia, if indicated.

- Fluid retention, which may lead to or exacerbate heart failure can occur with concomitant use of thiazolidinediones (TZDs) with insulin. These patients should be observed for signs and symptoms of heart failure. If heart failure develops, dosage reduction or discontinuation of the TZD must be considered.
- Do not dilute or mix Insulin Glargine-yfgn with any other insulin or solution. If mixed or diluted, the solution may become cloudy, and the onset of action/time to peak effect may be altered in an unpredictable manner. Do not administer Insulin Glargine-yfgn via an insulin pump or intravenously because hypoglycemia can occur.
- A reduction in the Insulin Glargine-yfgn dose may be required in patients with renal or hepatic impairment.

Refer to full Prescribing Information for insulin glargine-yfgn 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 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.

About Civica, Inc.:

Civica is a non-profit generic pharmaceutical company established in 2018 to address drug shortages. It was founded by a group of U.S. health systems and philanthropies who, after more than a decade of chronic shortages, recognized that the market was not self-correcting and that a different approach is required. Civica works to deliver a safe, stable, and affordable supply of essential medicines to U.S. patients. Civica has built a sterile injectable manufacturing plant in Petersburg, Virginia capable of producing prefilled pens and vials of insulin.
Website: www.civicarx.org Follow us on **X** (formerly Twitter) @civicarx and **LinkedIn**: CivicaRx 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	
MEDIA	**INVESTORS**
Rumman Ahmed Associate Director – Biocon Biologics +91-9845104173 rumman.ahmed@biocon.com **Lance Longwell** Public Relations Lead – Advanced Markets +1 857 270 4391 lance.longwell@biocon.com	**Saurabh Paliwal** Head - Investor Relations Biocon +91 95383 80801 saurabh.paliwal@biocon.com
For More Information: Civica **Liz Power** Vice President, Communications +1 860 501 3849 liz.power@civicarx.org	