

## Press Release

# **Biocon Biologics' First-Ever Interchangeable Biosimilar Insulin Glargine, Co-Developed with Commercial Partner Viatris, Preferred on Express Scripts' Largest Formulary in US**

**Express Scripts, a leading pharmacy benefit management organization, will list Viatris labelled biosimilar Insulin Glargine as a preferred insulin brand on its National Preferred Formulary® (NPF) that includes more than 28 million lives in the USA**

**Biocon Biologics & Viatris's interchangeable biosimilar Insulin Glargine injection will help increase access to this critical treatment for millions of Americans living with diabetes**

**Bengaluru, Karnataka, India – October 21, 2021**

**Biocon Biologics Limited (BBL)**, a subsidiary of Biocon Ltd. today announced that Express Scripts, a leading pharmacy benefit management organization in the US, will list Biocon Biologics interchangeable biosimilar Insulin Glargine (Semglee\*), which will be commercialized by Viatris, as a preferred glargine brand on its National Preferred Formulary® (NPF), which includes more than 28 million lives.

Broad coverage of Semglee® by Express Scripts will help ensure that the many patients on its network who need Insulin Glargine may receive the full benefits of and access to treatment with lower or maintained out-of-pocket costs.

Biocon Biologics co-developed Semglee with Viatris and together they are committed to improving patients' access to sustainable, high-quality and affordable biosimilars. As part of this commitment, Viatris will soon commercialize two versions of our landmark Insulin Glargine injection, the first-ever interchangeable biosimilar approved by the U.S. Food and Drug Administration (FDA): Semglee® (insulin glargine-yfgn) injection, a branded interchangeable product, and Insulin Glargine (insulin glargine-yfgn) injection, an authorized interchangeable biosimilar. Both products will be available in pen and vial

presentations and are interchangeable for the reference brand, Lantus®. Semglee will also be included in Express Scripts' Patient Assurance Program.

This dual product approach is intended to ensure that this historic interchangeable biosimilar insulin glargine can reach as many patients as possible regardless of financial circumstances, insurance or channel.

**Commenting on this marquee development, Dr Arun Chandavarkar, Managing Director, Biocon Biologics said :**

*“The inclusion of our interchangeable biosimilar insulin glargine in Express Scripts’ National Preferred Formulary® (NPF) in the U.S. is a major milestone for Biocon Biologics. It furthers our mission of enabling affordable access to quality insulins to a large number of patients. We expect our partner to commercialize the product in the U.S. by end of the year and formulary coverage to begin in Jan 2022, making it an important growth driver for Biocon Biologics.”*

*“We believe adoption of biosimilars through PBMs like Express Scripts, will drive down the high cost of biologics therapy for chronic diseases like diabetes. Our biosimilar Insulin Glargine has the potential to bring significant cost savings for patients, employers and PBMs,”* he added.

In July 2021, the U.S. Food and Drug Administration (FDA) had approved our biosimilar Insulin Glargine-yfng injection (Semglee®) as the first interchangeable biosimilar product under the 351(k) regulatory pathway, endorsing our scientific excellence and robust quality comparability data.

Semglee\* (insulin glargine-yfng) Injection and Insulin Glargine-yfng Injection will be available in pharmacies before the end of the year, and further details related to our partner Viatrix’ access programs, which aim to ensure that as many patients as possible will benefit from the product, will be available at that time.

The Express Scripts formulary change, including coverage of Semglee\* (insulin glargine-yfng) on NPF, will occur effective January 1, 2022.

Express Scripts, Inc. is one of the largest PBMs in North America, providing services to thousands of client groups, including managed-care organizations, insurance carriers, employers, third-party administrators, public sector, workers compensation, and union-sponsored benefit plans.

Pharmacy benefit managers, or PBMs, are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers.

*\*Biosimilar insulin glargine co-developed with Viatrix*

### **Indications and Important Safety Information**

Semglee is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with Type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. It is not recommended for the treatment of diabetic ketoacidosis. Do not use during episodes of hypoglycemia or if hypersensitive to insulin glargine or its excipients. Patients should be instructed to never share the prefilled pen even if the needle is changed. Changes to a patient's insulin regimen should be done under close medical supervision with increased frequency of blood glucose monitoring as hyper- or hypoglycemia may occur. Hypoglycemia is the most common adverse reaction with insulin, including Semglee and it may be life-threatening. Increase frequency of glucose monitoring when there are changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairment and hypoglycemia unawareness. Patients and caregivers must be educated to recognize and manage hypoglycemia. Medication errors can result from accidental mix-ups among insulin products. Instruct patients to always check the insulin label before injection. Severe, life-threatening generalized allergy, including anaphylaxis can occur with insulin products, including Semglee. If hypersensitivity reaction occurs, discontinue Semglee and treat per standard of care and monitor until symptoms and signs resolve. Monitor potassium levels for hypokalemia and treat if indicated. Fluid retention and heart failure have been reported with concomitant use of thiazolidinediones (TZD). Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation of TZD if heart failure occurs.

### **About Interchangeability**

An interchangeable biosimilar may be substituted for a reference product and may provide patients with greater access and drive conversion to biosimilars at the pharmacy counter.

### **About Biocon Biologics Limited**

Biocon Biologics Limited, a subsidiary of Biocon Limited, is a fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology, and other non-



communicable diseases. Five molecules from Biocon Biologics’ portfolio have been taken from lab to market, in developed markets like United States, EU, Australia, Canada, Japan and key emerging markets. It has many firsts to its credit including the most recent USFDA approval of world’s first interchangeable biosimilar, received for its Insulin Glargine. With a team of ~ 4,800 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients’ worldwide. Website: [www.biocon.com/businesses/biosimilars/](http://www.biocon.com/businesses/biosimilars/); **Follow us on Twitter:** [@BioconBiologics](https://twitter.com/BioconBiologics)

### About Biocon Limited

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 and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. Website: [www.biocon.com](http://www.biocon.com); Follow-us on Twitter: [@bioconlimited](https://twitter.com/bioconlimited)

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### 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.