



Intimation to Stock Exchange

## **Biocon Biologics and Viatris Announce Prime Therapeutics Prefers First-Ever Interchangeable Insulin Biosimilar Semglee® (insulin glargine-yfgn) Injection and Insulin Glargine (insulin glargine-yfgn) Injection on its National Formularies**

**November 4, 2021**

**Biocon Biologics Limited (BBL)**, a subsidiary of Biocon Ltd., and its partner Viatris Inc. are proud to confirm that Prime Therapeutics, a leading pharmacy benefit manager (PBM) in the US, serving nearly 33 million members, will list Semglee® (insulin glargine-yfgn) injection, a branded product, and Insulin Glargine (insulin glargine-yfgn) Injection, an unbranded product, as preferred insulin over the Lantus® brand on its national formularies. Broad coverage of the products, starting January 1, 2022, will help ensure that millions of patients in the Prime Therapeutics network who need insulin receive the full benefits of and access to high-quality treatment with lower or consistent out-of-pocket costs. Interchangeability allows for substitution for the reference product at the pharmacy counter.

This decision by Prime Therapeutics follows the U.S. Food and Drug Administration's (FDA) approval of the first-ever interchangeable biosimilar through the interchangeable pathway. As part of its commitment to patients, Biocon Biologics' partner Viatris will introduce the two (branded and unbranded) products, both of which will be available in pen and vial presentations and are interchangeable for the reference brand, Lantus®. Biocon Biologics and Viatris co-developed the products, and together the companies are committed to improving patients' access to sustainable, high-quality and affordable healthcare.

Semglee® (insulin glargine-yfgn) injection and Insulin Glargine (insulin glargine-yfgn) Injection will be available before the end of the year, and further details related to Viatris' access programs, which aim to ensure that as many patients as possible will benefit from the product, will be available at that time. Biocon Biologics and Viatris together are committed to ensuring that this historic interchangeable biosimilar insulin can reach as many patients as possible regardless of financial circumstances, insurance or channel.

## **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, coadministered 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 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)



## About Viatris

Viatrix Inc. (NASDAQ: VTRS) is a new kind of healthcare company, empowering people worldwide to live healthier at every stage of life. We provide access to medicines, advance sustainable operations, develop innovative solutions and leverage our collective expertise to connect more people to more products and services through our one-of-a-kind Global Healthcare Gateway®. Formed in November 2020, Viatrix brings together scientific, manufacturing and distribution expertise with proven regulatory, medical and commercial capabilities to deliver high-quality medicines to patients in more than 165 countries and territories. Viatrix' portfolio comprises more than 1,400 approved molecules across a wide range of therapeutic areas, spanning both non-communicable and infectious diseases, including globally recognized brands, complex generic and branded medicines, a growing portfolio of biosimilars and a variety of over-the-counter consumer products. With a global workforce of over 40,000, Viatrix is headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at [viatris.com](http://viatris.com) and [investor.viatris.com](http://investor.viatris.com), and connect with us on Twitter at @ViatrisInc, LinkedIn and YouTube.

## 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.

## Forward-Looking Statements: Viatrix

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements about Prime Therapeutics, a leading pharmacy benefit manager (PBM) serving nearly 33 million members, will list Semglee® (insulin glargine-yfng) injection, a branded product, and Insulin Glargine (insulin glargine-yfng) Injection, an unbranded product, as preferred insulin over the Lantus® brand on its national formularies; that broad coverage of the products, starting January 1, 2022, will help ensure that millions of patients in the Prime Therapeutics network who need insulin receive the full benefits of and access to high-quality treatment with lower or consistent out-of-pocket costs; that Viatrix will introduce the two (branded and unbranded) products, both of which will be available in pen and vial presentations and are interchangeable for the reference brand, Lantus®; that Semglee® (insulin glargine-yfng) injection and Insulin Glargine (insulin glargine-yfng) Injection will be available before the end of the year, and further details related to Viatrix' access programs, which aim to ensure that as many patients as possible will benefit from the product, will be available at that time; and that Viatrix is committed to ensuring that this historic interchangeable biosimilar insulin can reach as many patients as possible regardless of financial circumstances, insurance or channel. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to: the potential impact of public health outbreaks, epidemics and pandemics, including the ongoing challenges and uncertainties posed by the COVID-19 pandemic; the integration of Mylan N.V. and Pfizer Inc.'s Upjohn business (the "Upjohn Business"), which combined to form Viatrix (the "Combination") and the implementation of our global restructuring initiatives being more difficult, time consuming or costly than expected, or being unsuccessful; the ability to achieve expected



benefits, synergies and operating efficiencies in connection with the Combination or its restructuring initiatives within the expected timeframe or at all; actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market, including but not limited to "at-risk" launches; Viatris' or its partners' ability to develop, manufacture and commercialize products; the scope, timing and outcome of any ongoing legal proceedings and the impact of any such proceedings; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations, including our operations in China; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties and matters beyond the control of management; and the other risks Viatris' filings with the Securities and Exchange Commission. Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this release other than as required by law.

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