Press Release

# Biocon Biologics and Viatris Inc. Receive Historic Approval for First Interchangeable Biosimilar Semglee® (insulin glargine-yfgn injection) for the Treatment of Diabetes

## Interchangeable Designation Allows Substitution at the Pharmacy Counter for Lantus® Across the U.S. to Help Increase Access to Medicines for People Living with Diabetes

## Company is Eligible for 12 Months of First Interchangeable Exclusivity from the Date of Commercial Launch

BENGALURU, India and PITTSBURGH – July 29, 2021 – **Biocon Biologics Ltd**. (a subsidiary of Biocon Ltd.) and Viatris Inc. (NASDAQ: VTRS) and today announced that the U.S. Food and Drug Administration (FDA) has approved **Semglee®** (insulin glargine-yfgn injection) as the first interchangeable biosimilar product under the 351(k) regulatory pathway.

**Biocon Biologics, Executive Chairperson, Kiran Mazumdar-Shaw** said: "*We are extremely proud to be the first to obtain approval of an interchangeable Biosimilar product in the U.S. It is a milestone achievement for both Biocon Biologics and our partner Viatris. This will allow pharmacy level substitution and thereby provide convenient and affordable access to Semglee, a quality Biosimilar Insulin Glargine*."

**Biocon Biologics Managing Director Arun Chandavarkar** said: "*This interchangeability approval for Semglee by the U.S. FDA, another first to our credit, is a testament to our scientific excellence and robust quality comparability data. This allows substitution at the pharmacy counter, thus expanding patient access and sets the stage for future approvals for our other insulin products."*

The interchangeable Semglee product, which will allow substitution of Semglee for the reference product, Lantus®, at the pharmacy counter, will be introduced before the end of the year. The company is eligible to have exclusivity for 12 months before the FDA can approve another biosimilar interchangeable to Lantus. Commercial preparations for launch are underway. Over the next few months, Viatris will transition the current product to the 351(k) interchangeable product.

Semglee is indicated to control high blood sugar in adults with Type 2 diabetes and adults and pediatric patients with Type 1 diabetes. It is not recommended for the treatment of diabetic ketoacidosis. Semglee has an identical amino acid sequence to Lantus and is approved for the same indications.

Viatris CEO Michael Goettler commented: "*We are extremely proud to achieve the industry's first approval of an interchangeable biosimilar product in the U.S., which will help broaden access to this important diabetes medicine for patients, physicians, payers and providers. This is yet another important milestone for our company that not only continues to underscore the strength of our internal scientific capabilities, but also supports our belief in the promising future of our company as we continue to work to identify innovative ways to increase access to complex treatments for patients.*"

Viatris President Rajiv Malik added: "*We are very pleased to have once again worked with the FDA to achieve the very historic approval of the first interchangeable biosimilar in the U.S. and are grateful to our partner, Biocon Biologics, for their collaboration in achieving this milestone. Our continued ability to break down barriers to access, bring forth first-to-market products and blaze new trails is a testament to the strength of our scientific, regulatory, operations and legal expertise as well as our focus on patients*."

Viatris and Biocon Biologic's insulin glargine has received regulatory approval in more than 60 countries around the world and was the third product approved by the FDA through the Viatris-Biocon Biologics collaboration.

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 it's 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 the Viatris and Biocon Biologics Collaboration

Viatris and Biocon Biologics have an exclusive collaboration for the development, manufacturing and commercialization of a broad portfolio of biosimilars and insulin analogs. Viatris has exclusive commercialization rights in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon Biologics has exclusive commercialization rights for Japan and certain emerging markets. Viatris and Biocon Biologics have co-exclusive commercialization rights in the rest of the world.

## 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 and Japan. 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.
www.biocon.com/businesses/biosimilars/
Follow-us on Twitter: @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; Follow-us on Twitter: @bioconlimited

## About Viatris

Viatris 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, Viatris 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. Viatris' 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 approximately 45,000, Viatris is headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on Twitter at @ViatrisInc, LinkedIn and YouTube.

## Forward-Looking Statements: Viatris

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 the approval for the first interchangeable biosimilar Semglee (insulin glargine-yfgn injection) for the treatment of diabetes; that interchangeable designation allows substitution at the pharmacy counter for Lantus® across the U.S. to help increase access to medicines for people living with diabetes; that the company is eligible for 12 months of first interchangeable exclusivity from the date of commercial launch; that this is yet another important milestone for our company that not only continues to underscore the strength of our internal scientific capabilities, but also supports our belief in the promising future of our company as we continue to work to identify innovative ways to increase access to complex treatments for patients; that our continued ability to break down barriers to access, bring forth first-to-market products and blaze new trails is a testament to the strength of our scientific, regulatory, operations and legal expertise as well as our focus on patients; that the interchangeable Semglee product, which will allow substitution of Semglee for the reference product, Lantus®, at the pharmacy counter, will be introduced before the end of the year; that the company is eligible to have exclusivity for 12 months before the FDA can approve another biosimilar interchangeable to Lantus; that commercial preparations for launch are underway; and that over the next few months, Viatris will transition the current product to the 351(k) interchangeable product. 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 Viatris (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.

## 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.

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