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July 29, 2021

To, The Manager BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 Scrip Code – 532523	To, The Manager National Stock Exchange of India Limited Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 Scrip Symbol - Biocon
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Subject: Press Release titled “Biocon Biologics and Viatris Inc. Receive Historic Approval for First Interchangeable Biosimilar Semglee® (insulin glargine-yfgn injection) for the Treatment of Diabetes”.

Dear Sir/Madam,

Pursuant to Regulation 30 of the SEBI (Listing Obligation and Disclosure Requirements) Regulations, 2015, please find enclosed the press release titled “**Biocon Biologics and Viatris Inc. Receive Historic Approval for First Interchangeable Biosimilar Semglee® (insulin glargine-yfgn injection) for the Treatment of Diabetes**”.

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**

Mayank Verma
Company Secretary and Compliance Officer

Enclosed:

- A. Press Release
- B. Press Release done by USFDA: FDA Approved First Interchangeable Biosimilar Insulin Product for treatment of Diabetes, also available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>



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 **Viatis 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.

Viатris 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."*

Viатris 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."*

Viатris 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 Viатris-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 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 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



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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FDA NEWS RELEASE

FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes

Availability of Insulin Products Will Help Increase Access and Potentially Lower the Cost of Insulin for People with Diabetes

For Immediate Release:

July 28, 2021

Today, the U.S. Food and Drug Administration approved the first interchangeable biosimilar insulin product, indicated to improve glycemic control in adults and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes mellitus. Semglee (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for), its reference product Lantus (insulin glargine), a long-acting insulin analog. Semglee (insulin glargine-yfgn) is the first interchangeable biosimilar product approved in the U.S. for the treatment of diabetes. Approval of these insulin products can provide patients with additional safe, high-quality and potentially cost-effective options for treating diabetes.

“This is a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs,” said Acting FDA Commissioner Janet Woodcock, M.D. **“Today’s approval of the first interchangeable biosimilar product furthers FDA’s longstanding commitment to support a competitive marketplace for biological products and ultimately empowers patients by helping to increase access to safe, effective and high-quality medications at potentially lower cost.”**

Biological products include medications for treating many serious illnesses and chronic health conditions, including diabetes. A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from, a biological product already approved by the FDA (also called the reference product). This means you can expect the same safety and effectiveness from the biosimilar as you would the reference product.

An interchangeable biosimilar product may be substituted for the reference product without the intervention of the prescriber. The substitution may occur at the pharmacy, a practice commonly called “pharmacy-level substitution”—much like how generic drugs are substituted for brand name drugs, subject to state pharmacy laws, which vary by state. Biosimilar and interchangeable biosimilar products have the potential to reduce health care costs, similar to how generic drugs have reduced costs. Biosimilars marketed in the U.S. typically have launched with initial list prices 15% to 35% lower than comparative list prices of the reference products.

More than 34 million people in the U.S. today have been diagnosed with diabetes, which is a chronic (long-lasting) health condition that affects how the body stores and uses sugars and other nutrients for energy. Most food is broken down into sugar (also called glucose) and released into the bloodstream. When blood sugar levels increase, it signals the pancreas to release insulin, which acts like a key to allow blood sugar to enter the body's cells for use as energy. With diabetes, the body doesn't make enough insulin to keep sugar levels regulated in the normal range.

“Access to affordable insulin is critical and long-acting insulin products, like insulin glargine, play an important role in the treatment of Types 1 and 2 diabetes mellitus,” said Peter Stein, M.D., director of the Office of New Drugs in the FDA’s Center for Drug Evaluation and Research. “The FDA’s high standards for approval mean health care professionals and patients can be confident in the safety and effectiveness of an interchangeable biosimilar product, just as they would for the reference product.”

All biological products are approved only after they meet the FDA's rigorous approval standards. The approval of Semglee (insulin glargine-yfgn) as biosimilar to, and interchangeable with Lantus (insulin glargine), is based on evidence that showed the products are highly similar and that there are no clinically meaningful differences between Semglee (insulin glargine-yfgn) and Lantus (insulin glargine) in terms of safety, purity and potency (safety and effectiveness). It also showed that Semglee (insulin glargine-yfgn) can be expected to produce the same clinical result as Lantus (insulin glargine) in any given patient and that the risks in terms of safety or diminished efficacy of switching between Semglee (insulin glargine-yfgn) and Lantus (insulin glargine) is not greater than the risk of using Lantus (insulin glargine) without such switching.

Semglee (insulin glargine-yfgn), offered in 10 mL vials and 3 mL prefilled pens, is administered subcutaneously once daily. Dosing of Semglee (insulin glargine-yfgn), like Lantus, should be individualized based on the patient's needs and should not be used during episodes of hypoglycemia (low blood sugar) or in patients with hypersensitivity to insulin glargine products. Also, like Lantus, Semglee (insulin glargine-yfgn) is not recommended for treating diabetic ketoacidosis. Semglee (insulin glargine-yfgn) may cause serious side effects, including hypoglycemia (low blood sugar), severe allergic reactions, hypokalemia (low potassium in blood) and heart failure. The most common side effects associated with insulin glargine products other than hypoglycemia include edema (fluid retention), lipodystrophy (pitting at the injection site), weight gain and allergic reactions, such as injection site reactions, rash, redness, pain and severe itching.

The FDA released [new materials \(/drugs/biosimilars/health-care-provider-materials\)](/drugs/biosimilars/health-care-provider-materials) for health care providers to enhance understanding about biosimilar and interchangeable biosimilar products, including a fact sheet about interchangeable biosimilar products.

The FDA granted approval of Semglee (insulin glargine-yfgn) to Mylan Pharmaceuticals Inc.

Related Information

- [Health Care Provider Materials | FDA \(/drugs/biosimilars/health-care-provider-materials\)](#).
- [Consumer Update \(/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices\)](#).
- [Biosimilar and Interchangeable Products | FDA \(/drugs/biosimilars/biosimilar-and-interchangeable-products\)](#).
- [Purple Book Database of Licensed Biological Products \(https://purplebooksearch.fda.gov/\)](#).
- [Insulin Gains New Pathway to Increased Competition | FDA \(/news-events/press-announcements/insulin-gains-new-pathway-increased-competition\)](#).

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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