



Press Release

Biocon Biologics and Viatriis Announce Launch of Interchangeable SEMGLEE® (insulin glargine-yfgn) Injection and Insulin Glargine (insulin glargine-yfgn) Injection

Branded and unbranded versions of the first-ever interchangeable biosimilar in the U.S. provide more affordable options for the millions of Americans living with diabetes

BENGALURU, India and PITTSBURGH – November 16, 2021 –

Biocon Biologics Ltd., a subsidiary of Biocon Ltd., and **Viatriis Inc.** (NASDAQ: VTRS) today announced the U.S. launch of interchangeable biosimilars SEMGLEE® (insulin glargine-yfgn) injection, a branded product, and Insulin Glargine (insulin glargine-yfgn) injection, an unbranded product, to help control high blood sugar in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes. Both biosimilar products are available in vial and prefilled pen presentations and are interchangeable for the reference brand, LANTUS® (insulin glargine), allowing for substitution at the pharmacy counter.

Shreehas Tambe, Deputy CEO, Biocon Biologics said: *“At Biocon Biologics we are committed to expanding access to high-quality, affordable biologics to patients worldwide. The launch of our interchangeable biosimilar insulin glargine in the U.S. by our partner Viatriis is in line with our aspiration to provide our biosimilar insulins to ‘one in five’ insulin dependent people with diabetes, globally. This is indeed a landmark event and along with the recent formulary listings, we believe it will allow us to improve accessibility, availability and adoption of biosimilars in the U.S. for the benefit of patients and the overall healthcare system.”*

Viatriis Head of North America Jose Cotarelo said: *“Viatriis has a long-standing commitment to improving patient access to sustainable, quality and more affordable healthcare. We are extremely proud to stay true to that promise by bringing to millions of people with diabetes these interchangeable insulin biosimilar treatment options. We are pleased to also offer a broad range of options to help patients, which are intended to maximize access to these important medicines, regardless of financial circumstances, insurance or channel.”*



SEMGLEE (insulin glargine-yfgn) and Insulin Glargine (insulin glargine-yfgn), co-developed by Biocon Biologics and ViatriS, are now available in the U.S. market. The currently marketed non-interchangeable SEMGLEE (insulin glargine) is anticipated to be phased out by the end of the 2021 calendar year.

To further expand access to insulins, ViatriS has established a range of options to help patients, including:

- **Patient Assistance Program**, which may provide free medicine to eligible patients with demonstrated financial need.
- [Copay Program](#) offered for eligible commercially-insured patients, which may help reduce out-of-pocket expenses on prescriptions to as little as \$0 per 30-day supply.
- [Voucher](#) for new patients to receive five (5) free 3 mL pens or two (2) free 10 mL vials.
- **Cash-Pay Programs** to reduce out-of-pocket costs when paying at the pharmacy counter.
- **Medicare Part D Senior Savings Model Insulin Medicare Savings Program**, with membership beginning in 2022, which limits patient out-of-pocket costs during all phases of coverage (deductible, initial coverage and coverage gap) to no more than \$35 for a month's supply.

For more information about SEMGLEE (insulin glargine-yfgn) and Insulin Glargine (insulin glargine-yfgn) for people in the U.S., please visit, www.semglee.com.

Indications and Important Safety Information

SEMGLEE (insulin glargine-yfgn) 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 (insulin glargine-yfgn) 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 (insulin glargine-yfng). If hypersensitivity reaction occurs, discontinue SEMGLEE (insulin glargine-yfng) 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](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; Follow us on Twitter: [@bioconlimited](https://twitter.com/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



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 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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