



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

November 16, 2021

**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**

PITTSBURGH and BENGALURU, India, Nov. 16, 2021 /PRNewswire/ -- [Viatris Inc.](#) (NASDAQ: VTRS) and Biocon Biologics Ltd. 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.

Viatris Head of North America Jose Cotarelo said: "Viatris 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."

Shreehas Tambe, dCEO, 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 Viatris, 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."

SEMGLEE (insulin glargine-yfgn) and Insulin Glargine (insulin glargine-yfgn), co-developed by Viatris and Biocon Biologics, 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](http://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-yfgn). If hypersensitivity reaction occurs, discontinue SEMGLEE (insulin glargine-yfgn) 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 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<sup>®</sup>. 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 38,000, Viatris 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](https://twitter.com/ViatrisInc), [LinkedIn](https://www.linkedin.com/company/viatris) and [YouTube](https://www.youtube.com/channel/UC9WtXW1YU5X0tYU5X0tYU5X).

#### **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/](http://www.biocon.com/businesses/biosimilars/)

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#### **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

#### **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 that Viatris and Biocon Biologics today announced the U.S. launch of interchangeable biosimilars, SEMGLEE<sup>®</sup> (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; that both biosimilar products are available in vial and prefilled pen presentations and are 'interchangeable for the reference brand, LANTUS<sup>®</sup> (insulin glargine), allowing for substitution at the pharmacy counter; 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; that the currently marketed non-interchangeable SEMGLEE (insulin glargine) is anticipated to be phased out by the end of the 2021 calendar year; and information about the range of options Viatris has established to help patients, including a patient assistance program, copay program, voucher, cash-pay programs, and Medicare Part D Senior Savings Model Insulin Medicare Savings Program. 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 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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VIATRIS MEDIA: Jennifer Mauer, +1.724.514.1968, Communications@viatriis.com, Jennifer.Mauer@viatriis.com; VIATRIS INVESTORS: Bill Szablewski, +1.724.514.1813, InvestorRelations@viatriis.com, William.Szablewski@viatriis.com; BIOCON BIOLOGICS MEDIA: Seema Ahuja, Sr. VP & Global Head of Communications & Corporate Brand, Biocon Group & Biocon Biologics, +91 80 2808 2222, +91 99723 17792, seema.ahuja@biocon.com; BIOCON BIOLOGICS INVESTORS: Nikunj Mall, Head, Investor Relations, Biocon Biologics, 91 998 777 4078, nikunj.mall@biocon.com