# Mylan and Biocon Biologics Announce Launch of Semglee™ (insulin glargine injection) in the U.S. to Expand Access for Patients Living with Diabetes

August 31, 2020

**Semglee available in vial and pen presentations at a 65% discounted list price, the lowest available for a long-acting insulin glargine on the market**

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, Aug. 31, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Biocon Biologics India Ltd., a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced the U.S. launch of Semglee™ (insulin glargine injection) in vial and pre-filled pen presentations, approved to help control high blood sugar in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes. It is not recommended for the treatment of diabetic ketoacidosis. Semglee, which received final approval from the U.S. Food and Drug Administration (FDA), has an identical amino acid sequence to Sanofi's Lantus® and is approved for the same indications.

**Dr. Thomas Blevins, M.D., lead investigator for the INSTRIDE clinical trials, said:** "The availability of Semglee provides another quality treatment option for patients living with diabetes in the U.S. We rigorously compared Semglee (insulin glargine injection) to the reference insulin glargine in participants with Type 1 and 2 diabetes and found that Semglee yielded similar (non-inferior) glycemic results in both groups. The safety, including immunogenicity, was similar too. As a result, this insulin was approved by the FDA for the same indications as its reference product Lantus, thus expanding access for millions of people within this important patient community."

To encourage broad patient access to this important medicine, Mylan is offering Semglee at a wholesale acquisition cost (WAC)[1] of $147.98 per package of five (5) 3ml pens and $98.65 per 10ml vial, representing the lowest WAC for any long-acting insulin glargine on the market. The list price of Semglee pen is equivalent to the Lantus launch price in 2007, and the Semglee vial is listed at Lantus's 2010 pricing. Eligible patients may also qualify for patient assistance and/or a co-pay card, similar to other medications in this class. Additionally, Mylan has submitted to FDA all necessary documentation to request approval of Semglee as a biosimilar to Lantus under the 351(k) pathway and remains confident in seeking an interchangeability designation.

**Mylan CEO Heather Bresch said**: "We are proud to be the first company, following the reference product, to receive FDA approval on and launch both the vial and pen presentations of an insulin glargine treatment with an identical amino acid sequence to Sanofi's Lantus®. Even more importantly, we are proud to make Semglee available to the more than 30 million Americans living with diabetes in the U.S.[2], providing more treatment options and increasing access. While providing our product at the most competitive list price on the market is an important step toward ensuring that those who need insulin are able to access and afford it, we also know that there is still work to be done to ensure this access and affordability reaches patients at the pharmacy counter. We remain committed to work across the healthcare system to improve outcomes for all."

**Mylan President Rajiv Malik said:** "Bringing to market both the vial and pen presentations of Semglee, the first for any company following the reference product, required years of investment and commitment, and represents another important example of the power of the unique platform we've built along with our partner Biocon Biologics in terms of our research and development, regulatory, legal and commercial expertise. Today's launch also furthers our continued efforts to serve patients through the availability of a full portfolio of short- and long-acting insulins, which also includes our insulin aspart that we expect to launch next year. Our near-term strategy to ensure the availability of Semglee will require a strategic and targeted phased launch approach. Over the long term, we expect this addition to our portfolio to play an increasingly important role within our global biosimilars and insulin analog franchise as well as our efforts to advance access to complex medicines."

**Kiran Mazumdar-Shaw**, **Executive Chairperson**, **Biocon said:** "The commercialization of our insulin glargine in the U.S. represents another milestone achievement for Biocon in making insulin-based therapy increasingly accessible for people with diabetes globally. We are confident that along with our long-standing partner Mylan, we will be able to address the needs of millions of patients living with diabetes in the U.S. Leveraging our science and global scale manufacturing expertise, we have been expanding affordable access to biosimilar insulins to patients in Japan, Australia, Europe, India and key emerging markets. The U.S. launch of Semglee takes us closer to realizing our aspiration of reaching 'one in five' insulin dependent people with diabetes worldwide."

**Dr. Christiane Hamacher**, **CEO**, **Biocon Biologics said:** "It is indeed a proud moment for Biocon Biologics to make Semglee (insulin glargine injection) available to patients in the U.S. Our unwavering focus on developing and manufacturing global quality insulins enables us to address the growing needs of diabetes patients and the healthcare systems. We stay committed to expand affordable access to life-saving global quality biosimilars and insulin analogs and generating savings for the U.S. healthcare system. We believe the U.S. market represents a great opportunity for us and expect Semglee to contribute significantly to our goal of impacting 5 million patients' lives and achieving $1 billion revenue by end of FY22."

The approval for Semglee was based on a comprehensive analytical, preclinical and clinical program (including the INSTRIDE studies) which confirmed the PK/PD, efficacy, safety profile and immunogenicity of Semglee as compared to Lantus in patients with type 1 and type 2 diabetes.

Today's launch follows favorable judgments on all remaining patent claims asserted by Sanofi against Mylan's insulin glargine products. Although Sanofi may seek certain appeals of those judgments, Mylan is confident they will not affect commercialization.

Sanofi's total IQVIA sales for the 12 months ending June 30, 2020 were approximately $1.64 billion for Lantus 100 Units/mL Vial and approximately $4.36 billion for Lantus SoloSTAR Pen.

Mylan and Biocon Biologic's insulin glargine has received regulatory approval in more than 45 countries around the world and is the third product approved by FDA through the Mylan-Biocon Biologics collaboration.

**About the INSTRIDE Studies**
The INSTRIDE 1 and INSTRIDE 2 studies were randomized, confirmatory clinical trials designed to evaluate the efficacy and safety of Mylan's proposed insulin glargine, MYL-1501D, versus branded insulin glargine, Lantus. INSTRIDE 1 was a 52-week noninferiority study in 558 T1DM patients, while INSTRIDE 2 was a 24-week study in 560 T2DM (including insulin-naïve) patients. In both studies, patients were randomized to receive either once daily MYL-1501D or Lantus and the primary endpoint was change from baseline in HbA1c after 24 weeks. Secondary endpoints included glycemic endpoints like change from baseline in fasting plasma glucose and insulin dose, as well as safety endpoints like systemic reactions, device-related safety issues and immunogenicity. The safety, efficacy and immunogenicity data from these studies in T1DM and T2DM patients indicated that there were no differences in the Semglee and Lantus arms.

**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 with 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 Mylan and Biocon Biologics Collaboration**
Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilars and insulin analogs. Mylan has exclusive commercialization rights for insulin glargine in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon Biologics has exclusive rights for Japan and a few emerging markets, and co-exclusive commercialization rights with Mylan in the rest of the world.

**About Mylan**
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

**About Biocon Biologics India Limited:**
Biocon Biologics India Limited (Biocon Biologics), a subsidiary of Biocon Ltd, is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. Building on the four pillars of Patients, People, Partners and Business, Biocon Biologics is committed to transforming healthcare and transforming lives. Biocon Biologics is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a platform of 28 biosimilar molecules across diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, of which three have been commercialized in developed markets like EU, Australia, United States, Canada and Japan. It aspires to benefit 5 million patient lives with its biosimilars and attain a revenue milestone of USD 1 billion in FY22. 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. www.biocon.com Follow-us on Twitter: @bioconlimited

**Forward-Looking Statements: Mylan**
This press release includes statements that constitute "forward-looking statements," including with regard to the launch of Semglee; that Semglee will be available in vial and pen presentations at a 65% discounted list price, the lowest available for a long-acting insulin glargine on the market; that to encourage broad patient access to this important medicine, Mylan is offering Semglee at a wholesale acquisition cost (WAC) of $147.98 per package of five (5) 3ml pens and $98.65 per 10ml vial, representing the lowest WAC for any long-acting insulin glargine on the market; that eligible patients may also qualify for patient assistance and/or a co-pay card, similar to other medications in this class; that additionally, Mylan has submitted to FDA all necessary documentation to request approval of Semglee as a biosimilar to Lantus under the 351(k) pathway and to seek an interchangeability designation; while providing our product at the most competitive list price on the market is an important step toward ensuring that those who need

insulin are able to access and afford it, we also know that there is still work to be done to ensure this access and affordability reaches patients at the pharmacy counter; bringing to market both the vial and pen presentations of Semglee, the first for any company following the reference product, required years of investment and commitment, and represents another important example of the power of the unique platform we've built along with our partner Biocon Biologics in terms of our research and development, regulatory, legal and commercial expertise; today's launch also furthers our continued efforts to serve patients through the availability of a full portfolio of short- and long-acting insulins, which also includes our insulin aspart that we expect to launch next year; our near-term strategy to ensure the availability of Semglee will require a strategic and targeted phased launch approach; over the long term, we expect this addition to our portfolio to play an increasingly important role within our global biosimilars and insulin analog franchise as well as our efforts to advance access to complex medicines; today's launch follows favorable judgments on all remaining patent claims asserted by Sanofi against Mylan's insulin glargine products; and that although Sanofi may seek certain appeals of those judgments, Mylan is confident they will not affect commercialization. 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 widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

**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.

[1] WAC does not necessarily reflect actual cost to healthcare system or patients.

[2] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2020.

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