Biocon and Mylan Announce U.S. FDA Approval of Semglee™ (insulin glargine injection)

- ***FDA approval marks a significant milestone to help increase access and affordability of insulin for the millions of Americans living with diabetes[1]***

- ***Comprehensive data from the INSTRIDE studies confirmed the efficacy, safety and immunogenicity of Semglee in comparison to Lantus®***

- ***Semglee to be offered in vial and pen presentations***

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India -- June 11/ 12, 2020 -- Biocon Ltd. (BSE code: 532523, NSE: BIOCON) and **Mylan N.V.** (NASDAQ: MYL) today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Semglee™ (insulin glargine injection), in vial and pre-filled pen presentations, to control high blood sugar in adults with type 2 diabetes and adult and pediatric patients with type 1 diabetes. Semglee has an identical amino acid sequence to Sanofi's Lantus® and is approved for the same indications.

Semglee, co-developed by Mylan and Biocon Biologics, was approved as a drug product under the 505(b)(2) NDA pathway and is now deemed a biologic under section 351(a) in accordance with the Biologics Price Competition and Innovation Act in line with other insulin products.

Kiran Mazumdar Shaw, Chairperson, Biocon, said: "*The approval of our insulin glargine by the U.S. FDA marks the culmination of a long journey. As an organisation committed to making insulin-based therapy increasingly accessible for people with diabetes globally, I am glad this approval will enable us to serve the needs of patients in the U.S. The approval is also an endorsement of our science, scale and expertise to develop high quality, more affordable insulins and shift the access paradigm in favour of patients, taking us closer to realizing our aspiration of reaching 'one in five' insulin dependent people with diabetes worldwide.*"

Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics, said, "*We are extremely excited with the opportunity to offer Semglee, co-developed with Mylan and manufactured by Biocon Biologics, to the U.S. market, where millions of patients need more affordable insulin analogs to control their diabetes. Our combined scientific expertise and global scale manufacturing capability complemented by a comprehensive product presentation across vials and pens will enable us to expand patient access to our insulin glargine through our partner Mylan. We are making a significant difference to patients in several countries across the world and commercialization of Semglee in the U.S. will further expand affordable access for patients with diabetes. Biocon Biologics is committed to impact 5 million patient lives globally by FY 22.*"

She added: "*The global INSTRIDE clinical studies have demonstrated no difference in safety, efficacy and immunogenicity of Semglee in comparison to the reference product, Lantus, in type 1 and type 2 diabetes. Our goal is to enable access to patients in need of insulins, and we are working towards creating a patient ecosystem that helps in lowering co-morbidities and achieving overall cost savings for the healthcare systems.*"

Mylan CEO Heather Bresch said: *"This approval is an important milestone, first and foremost for the millions of patients living with diabetes in the U.S. as we seek to expand their access to insulin through more affordable treatment options. It's also another milestone for Mylan as we continue to leverage our scientific, commercial, manufacturing and regulatory expertise to benefit patients, and as we enhance our portfolio with increasingly complex and higher value-chain products, like insulin. Leveraging these capabilities, whether through our internal teams or through strong partnerships like the one we've built with Biocon, strengthens our ability to deliver innovative solutions to patients in the U.S. and around the world."*

Mylan President Rajiv Malik added: "*Today's milestone makes Mylan the first company to have approvals on both the vial and pen presentations of insulin glargine treatment options to Lantus® and further reaffirms our proven scientific track record in gaining approval for complex products like Glatiramer Acetate, Yupelri®, biosimilars to Neulasta® and Herceptin®, as well as a drug-device combination product like Wixela® Inhub®. I would like to recognize the extraordinary work and leadership of both Mylan and Biocon's scientific and regulatory teams for this achievement. As a leading provider of oral diabetes medicine in the U.S., this approval expands our offerings to those living with the disease while further demonstrating the power of the unique platform we've built in terms of scientific excellence, strong partnerships and the ability to leverage our regulatory and commercial expertise around the world to bring higher value-chain products to market. Semglee represents another component to our global biosimilars franchise approach in advancing access to complex medicines."*

Malik continued, *"Additionally, we believe that the strong comprehensive analytical and clinical program supporting the approval of Semglee will be central to our continued work to achieve interchangeable product status, with the potential to further reduce the cost burden for patients. We look forward to making this product available to patients in the U.S. as soon as possible."*

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 and immunogenicity of Semglee in comparison to Lantus in patients with type 1 and type 2 diabetes.

Favorable judgments on all remaining patent claims asserted by Sanofi against Mylan's insulin glargine products have been obtained. Although Sanofi may seek certain appeals of those judgments, Mylan is confident they will not affect commercialization plans.

Sanofi's total IQVIA sales for the 12 months ending April 30, 2020 were approximately $1.68 billion for Lantus 100 Units/mL Vial and approximately $4.33 billion for Lantus SoloSTAR Pen.

Mylan and Biocon Biologics 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 supervision with increased 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. 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 administration. 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. Fluid retention and heart failure have been reported with concomitant use of thiazolidinediones and Semglee.

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.

Notes: [1]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.

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

Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company's portfolio of biosimilar molecules comprises a rich pipeline of approved and in-development biosimilars, which are an outcome of its high end R&D and global scale manufacturing expertise. The Company has commercialized three of its biosimilars in the developed markets like EU, U.S., Japan and Australia. It is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. Follow-us on Twitter: @BioconBiologics

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.

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.

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to the regulatory approval commercialization of products; the potential outcome of litigation; that Semglee is to be offered in vial and pen presentations; that this is another milestone for Mylan as we continue to leverage our scientific, commercial, manufacturing and regulatory expertise to benefit patients, and as we enhance our portfolio with increasingly complex and higher value-chain products, like insulin; that leveraging these capabilities, whether through our internal teams or through strong partnerships like the one we've built with Biocon, strengthens our ability to deliver innovative solutions to patients in the U.S. and around the world; that today's milestone makes Mylan the first company to have approvals on both the vial and pen presentations of insulin glargine treatment options to Lantus® and further reaffirms our proven scientific track record in gaining approval for complex products like Glatiramer Acetate, Yupelri®, biosimilars to Neulasta® and Herceptin®, as well as a drug-device combination product like Wixela® Inhub®; that as a leading provider of oral diabetes medicine in the U.S., this approval expands our offerings to those living with the disease while further demonstrating the power of the unique platform we've built in terms of scientific excellence, strong partnerships and the ability to leverage our regulatory and commercial expertise around the world to bring higher value-chain products to market; that Semglee represents another component to our global biosimilars franchise approach in advancing access to complex medicines,; we believe that the strong comprehensive analytical and clinical program supporting the approval of Semglee will be central to our continued work to achieve interchangeable product status, with the potential to further reduce the cost burden for patients; we look forward to making this product available to patients in the U.S. as soon as possible; that favorable judgments on all remaining patent claims asserted by Sanofi against Mylan's insulin glargine products have been obtained; and although Sanofi may seek certain appeals of those judgments, Mylan is confident they will not affect commercialization plans. 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.

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