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Mylan and Biocon Announce Regulatory Submission for Insulin Glargine Accepted for Review by European Medicines Agency

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India, Nov. 3, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the European Medicines Agency (EMA) has accepted for review Mylan's Marketing Authorization Application (MAA) for insulin glargine, a long-acting insulin analog used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.

Mylan and Biocon, which have co-developed insulin glargine, look forward to offering another insulin treatment option for diabetic patients, who are often facing significant expense to manage their disease.

This filing includes analytical, functional and pre-clinical data, as well as results from the pharmacokinetics (PK) and confirmatory efficacy/safety global clinical trial in Type 2 diabetes patients comparing Mylan's and Biocon's Insulin glargine with Lantus. The PK study demonstrated PK and PD bioequivalence of Mylan's and Biocon's insulin glargine relative to that of the reference drug Lantus.

Mylan President Rajiv Malik commented: "The acceptance of our regulatory submission for insulin glargine in Europe is yet another example of the strong progress we continue to make across the exciting portfolio of complex products we have in development, and is another demonstration of the success of our partnership with Biocon. Fifteen percent of the world's pharmaceutical spend will be on diabetes medicines by 2020[1] and there is a significant unmet need around the world for more affordable versions of injectable insulin products. We look forward to helping serve this patient population, building on our existing strength in oral diabetic drugs, by bringing this product to the European market and other markets around the world upon approval."

Dr Arun Chandavarkar, CEO & Joint MD, Biocon, commented: "The acceptance of the insulin glargine application for review by the EMA is another important milestone in Biocon's collaboration with Mylan. This is the third filing from our portfolio comprising biosimilar monoclonal antibodies, insulin analogs and other recombinant proteins to be accepted by EMA in 2016. Importantly, this is the first

filing in a developed market that incorporates product validated at our state-of-the-art Malaysia facility and takes us a step closer to our mission of improving access to more affordable insulins globally."

About Biocon and Mylan Partnership
Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. Glargine is one of the three insulin analogs being co-developed by Mylan and Biocon for the global marketplace. 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 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 growing portfolio of more than 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 40,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com

About Biocon
Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 100 countries, it is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of Novel Biologics, Biosimilars, differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'. Some of its key brands are INSUGEN® (rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin analog.

Forward-Looking Statement: Mylan
This press release includes statements that constitute "forward-looking statements," including with regard to regulatory filings; Mylan offering another insulin treatment option for diabetic patients; Mylan's portfolio of complex products in development; Mylan's partnership with Biocon; future pharmaceutical spend; and plans to bring the product to European and other markets. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or

other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; 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; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; 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 Statement: Biocon

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, 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 biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither our company, our directors, nor any of our affiliates, have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

[1] IMS Institute report, "Global Medicines Use in 2020," Nov. 2015

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For further information: MYLAN, Nina Devlin (Media), 724.514.1968, Email: Nina.Devlin@mylan.com, Kris King (Investors), 724.514.1813, Email: Kris.King@mylanlab.com; BIOCON, Seema Ahuja (Media), +91-80-2808-2222; M:+91 99723 17792, Email: seema.ahuja@biocon.com, Saurabh Paliwal (Investors), +91 80 6775 2040; M:+91 95383 80801, Email: saurabh.paliwal@biocon.com