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Mylan and Biocon Present Clinical Data on Insulin Glargine at the American Diabetes Association's 77th Scientific Sessions

Data Show Comparable Efficacy, Safety and Immunogenicity to Lantus® in Type 1 and Type 2 Diabetes Patients

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, June 10, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced the presentation of new data from the insulin glargine clinical program, including the INSTRIDE studies at the American Diabetes Association's 77th Scientific Sessions in San Diego. The studies confirmed the efficacy, safety and immunogenicity of MYL-1501D, insulin glargine, in comparison to Lantus® in patients with Type 1 and Type 2 diabetes. Data demonstrating pharmacokinetic and pharmacodynamic equivalence also was presented.

Mylan
Better Health for a Better World®

Insulin glargine is a long-acting insulin used to treat adults with Type 2 diabetes, as well as adults and pediatric patients with Type 1 diabetes, for the control of high blood sugar.

Mylan President Rajiv Malik commented, "With more than 29 million Americans living with diabetes* and the cost of insulin products on the rise, there's a clear unmet need for more-affordable treatment options for insulin glargine. We are pleased with the positive results of the INSTRIDE clinical program, which demonstrate comparable clinical efficacy and safety of our insulin glargine to Lantus. We have long been deeply committed to supporting this community and advancing treatment for patients as the leading producer of oral diabetes medications in the U.S., and now we are continuing to deliver on our mission through our insulin programs."

Arun Chandavarkar, CEO & Joint Managing Director, Biocon, added, "We are pleased with the outcome of these global clinical studies confirming the safety, efficacy and immunogenicity of our insulin glargine in comparison to the reference product in Type 1 and Type 2 diabetes. This is an important milestone in our development of a more affordable insulin glargine and furthers our mission of enabling access by addressing the needs of diabetes patients globally."

Data will be presented during the poster session at 11:30 a.m. PT today.

- **Comparative Pharmacokinetics (PK) and Pharmacodynamics (PD) of a Proposed Biosimilar Insulin Glargine and Lantus in Patients with Type 1 diabetes (T1D)** (Poster #1019-P)

- **Efficacy and safety of MYL-1501D (Mylan's insulin glargine) compared with Lantus® (Sanofi's insulin glargine) in patients with Type 1 diabetes after 52 weeks: The INSTRIDE 1 study** (Poster #1018-P)
- **Efficacy and safety of MYL-1501D (Mylan's insulin glargine) compared with Lantus® (Sanofi's insulin glargine) in patients with Type 2 diabetes after 24 weeks: The INSTRIDE 2 study** (Poster #1017-P)
- **Comparable Immunogenicity between MYL-1501D (Mylan's insulin glargine) and Lantus® (Sanofi's insulin glargine) in Patients with Type 1 and 2 Diabetes Mellitus: The Phase 3 INSTRIDE studies** (Poster #1028-P)

Full session details and abstracts for the 2017 Scientific Sessions can be found on the American Diabetes Association's website at professional.diabetes.org/meeting/scientific-sessions/77th-scientific-sessions.

*Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.

About the INSTRIDE Studies

The two INSTRIDE studies were randomized, confirmatory clinical trials designed to evaluate comparative efficacy and safety of Mylan's proposed insulin glargine, MYL-1501D versus branded insulin glargine, Lantus®. INSTRIDE1 was a 52-week 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.

About the Mylan and Biocon Collaboration

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 market a growing portfolio of more than 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world 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 more than 35,000-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 120 countries, it is committed to reduce therapy costs of chronic diseases like diabetes, autoimmune and cancer. 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.
Visit: www.biocon.com

Forward-Looking Statement: Mylan
This press release includes statements that constitute "forward-looking statements," including with regard to the presentation of data, future plans and expectations and product development. 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; 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 Statement: 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.

SOURCE Mylan N.V.

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