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Mylan and Biocon Announce Regulatory Submission for Proposed Biosimilar Pegfilgrastim Accepted for Review by European Medicines Agency

BENGALURU, India, HERTFORDSHIRE, England and PITTSBURGH, July 21, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) announced today that the European Medicines Agency (EMA) has accepted for review, Mylan's Marketing Authorization Application (MAA) for our proposed biosimilar Pegfilgrastim, which is used to reduce the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Mylan and Biocon, who have co-developed the proposed biosimilar, received EMA's acceptance of the submission for review. In addition to analytical, functional and pre-clinical data, the application includes clinical data from pivotal Pharmacokinetic / Pharmacodynamic (PK / PD) and confirmatory efficacy, safety and immunogenicity studies completed earlier in 2016. The results from the studies are expected to be presented at the prestigious European Society of Medical Oncology (ESMO) Annual Congress to be held in Copenhagen in Oct. 2016.

Arun Chandavarkar, CEO and Joint Managing Director, Biocon, said: "The regulatory submission of biosimilar Pegfilgrastim with the EMA by our partner Mylan marks another significant milestone in our journey to develop affordable biologics for cancer patients. Once approved, this product will enable enhanced access to a cost-effective alternative for patients undergoing chemotherapy in the EU. We are committed to bring a diversified portfolio of high-quality, life-enhancing biosimilars to patients globally."

Mylan President Rajiv Malik commented: "We continue to make great progress across our biosimilars portfolio, which represents one of the industry's largest and most diversified portfolios in development. This milestone in our Pegfilgrastim program represents yet another important step in bringing more affordable versions of these critical products to market, with Europe representing an exciting opportunity for Mylan in this area."

Pegfilgrastim is prescribed for cancer patients to help them with some of the side-effects of their treatment. It reduces the duration of neutropenia (low levels of neutrophils, a type of white blood cell that fights infections) and the incidence of febrile neutropenia (neutropenia with fever) that are a result of their chemotherapy treatment.

Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and generic insulin analogs.

The proposed biosimilar Pegfilgrastim is one of the six biologic products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the proposed biosimilar Pegfilgrastim in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon has co-exclusive commercialization rights with Mylan for the product 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 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 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 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 100 countries, it is committed to reduce therapy costs of chronic diseases like autoimmune, diabetes, 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 proposed biosimilar, once approved, enabling Biocon and Mylan to provide access to biosimilar Pegfilgrastim as a more cost-effective alternative for patients undergoing cancer treatment in EU; Biocon and Mylan's commitment to bringing a diversified portfolio of biosimilars to a global patient pool; Mylan's biosimilars portfolio; opportunities in Europe with respect to biosimilars; and the expected presentation of trial results. 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 biosimilars; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring biosimilar candidates to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights, including with respect to biosimilar candidates; 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.

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