Press Release

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

BENGALURU, India and HERTFORDSHIRE, England/PITTSBURGH, USA, August 25, 2016

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 a proposed biosimilar Trastuzumab, which is used to treat certain HER2-positive breast and gastric cancers. This is the second biosimilar submission developed by the partnership that has been accepted for review in Europe. Last month, Mylan's MAA for the proposed biosimilar Pegfilgrastim was accepted for review by EMA.

Mylan and Biocon, which have co-developed this proposed biosimilar, anticipate that this may be the first MAA for a Trastuzumab biosimilar accepted by the EMA for review.

This filing includes analytical, functional and pre-clinical data, as well as results from the pharmacokinetics (PK) and confirmatory efficacy/safety global clinical trials for Trastuzumab. The PK study had demonstrated measured bioequivalence of Mylan's and Biocon's proposed Trastuzumab biosimilar relative to that of the reference drug. The second study, the 'HERITAGE Study', evaluated the efficacy, safety and immunogenicity of the proposed biosimilar Trastuzumab in comparison to branded Trastuzumab.

Mylan President Rajiv Malik commented: *"The acceptance of our regulatory submission of our proposed biosimilar Trastuzumab in Europe is another example of the strong progress we continue to make across our broad biosimilars portfolio. Following our successful commercialization in India and emerging markets, we look forward to our pending launch in Europe. Europe represents a key market for more affordable versions of these important products, as governments across the region strive to reduce healthcare costs. We look forward to continuing to work to bring this product to patients upon approval."*

Arun Chandavarkar, CEO and Joint Managing Director, Biocon, said: *"The regulatory submission for proposed biosimilar Trastuzumab in Europe takes us a step closer towards enabling affordable access to this critical biologic therapy for the treatment of HER2-positive breast cancer. We remain committed to bring a diversified portfolio of high-quality, life-enhancing biosimilars to patients globally."*

At the annual American Society of Clinical Oncology (ASCO) event held in June this year, 24 week data for the 'HERITAGE' study was presented. The results of the 48 week extension data of the 'HERITAGE' study are expected to be presented at the upcoming European Society for Medical Oncology Congress (ESMO) in October.

About Biocon and Mylan Partnership

Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. The proposed biosimilar Trastuzumab 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 Trastuzumab in the U.S., Canada, Japan, Australia, New Zealand, 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 HER2-Positive Breast Cancer and Trastuzumab

Worldwide, nearly 2 million women are diagnosed with breast cancer each year, making it the second most common cancer in the world. HER2-positive breast cancer is an aggressive form of breast cancer that tests positive for the human epidermal growth factor receptor 2 (HER2), which promotes cancer cell growth. Approximately 20% to 30% of primary breast cancers are HER2-positive. Trastuzumab is indicated for the treatment of certain HER2-positive early stage and metastatic breast cancer as well as HER2-positive metastatic gastric cancer.

About the Heritage Study

The Phase III study, HERITAGE, is a double-blind, randomized clinical trial designed to evaluate comparative efficacy and safety of the proposed Trastuzumab biosimilar, MYL-1401O, versus branded Trastuzumab. Eligible patients had centrally confirmed, measurable HER2-positive metastatic breast cancer without prior chemotherapy or Trastuzumab for metastatic disease. Patients were randomized to receive either MYL-1401O or branded Trastuzumab with docetaxel or paclitaxel for a minimum of eight cycles. Trastuzumab was continued until progression. The primary endpoint is overall response at week 24 by blinded central evaluation using RECIST 1.1. Secondary endpoints include progression free survival, overall survival, and safety. A sample size of 456 patients was calculated to demonstrate equivalence in overall response at week 24 for MYL-1401O versus branded Trastuzumab, defined as a 90% confidence interval for the ratio of best overall response rate within the equivalence margin (0.81, 1.24). This study successfully met the predefined equivalence criteria. The response rates at 24 weeks were 69.6% with MYL-1401O combined with taxane chemotherapy versus 64% with branded Trastuzumab combined with taxane chemotherapy. The incidence of adverse events was similar in the patients who received MYL-1401O and those who received reference Trastuzumab.

About Biosimilars

A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine and has demonstrated no clinically meaningful differences in safety, purity, and potency compared to that of the reference biologic. A biosimilar product and its reference biologic product are expected to have the same safety and efficacy profile and are generally used to treat the same conditions. Biosimilars may offer a less-costly alternative to existing biological medicinal products that have lost their exclusivity rights.

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 in the developing world 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 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.

Forward-Looking Statement: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to the belief that Mylan may have submitted the first MAA for a Trastuzumab biosimilar that has been accepted by the EMA for review; the proposed biosimilar, once approved, enabling Biocon and Mylan to provide access to a Trastuzumab biosimilar 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 the results of the 48 week extension data of the 'HERITAGE' study.. 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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