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Journal of the American Medical Association (JAMA) Publishes Mylan and Biocon's Proposed Biosimilar Trastuzumab Phase 3 Data

HERITAGE Study Results Demonstrate Equivalent Overall Response Rate for MYL-1401O in Comparison to Branded Trastuzumab

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, Dec. 27, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the results of the HERITAGE study have been published in the Journal of the American Medical Association (JAMA). Study results confirm the efficacy, safety and immunogenicity of MYL-1401O, the proposed biosimilar trastuzumab co-developed by Mylan and Biocon, in comparison to branded trastuzumab. The results of the trial were first presented at this year's American Society of Clinical Oncology (ASCO) Annual Meeting and the European Society for Medical Oncology (ESMO) Congress. Branded trastuzumab is indicated to treat certain HER2-positive breast and gastric cancers.

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Dr. Hope S. Rugo, professor of medicine at the University of California, San Francisco, commented: "We are encouraged by the confirmatory efficacy and safety results of the HERITAGE study recently published in JAMA. This study was the last major step of a multiple-phased program to demonstrate that proposed biosimilar trastuzumab meets the criteria for equivalence in comparison to branded trastuzumab. Published study results showed an overall response rate of 69.6% for MYL-1401O compared to 64% for branded trastuzumab. Tumor progression, progression-free survival and overall survival was not statistically different between proposed biosimilar trastuzumab and branded trastuzumab at week 48."

Mylan President Rajiv Malik added: "We are proud that JAMA has recognized the results of the HERITAGE study and are encouraged that the proposed biosimilar trastuzumab, MYL-1401O, could provide an effective treatment option for metastatic breast cancer patients. Phase 3 study results show that a biosimilar can deliver similar efficacy in comparison to a branded product. Once approved, we believe our proposed biosimilar trastuzumab will provide a lower cost treatment option for breast cancer patients. We look forward to continuing our industry-leading role with Biocon to expand patient access across the globe to this critically important medicine as well as Mylan's broad portfolio of 15 additional biologics and insulin analogs currently in development."

Dr. Narendra Chirmule, Sr. Vice President & Head R&D, Biocon, said: "The development of biosimilars requires a systematic scientific approach from design of the process to development. Biocon and Mylan have a scientifically rigorous, ethically compliant and structured development strategy to establish comparative safety and efficacy of our products. The global clinical progress of our various biosimilars programs demonstrates the strength of our R&D capabilities in this area. We are pleased that JAMA has published the clinical study results of trastuzumab after its very rigorous peer review process."

The HERITAGE data was submitted by Mylan to the U.S. Food and Drug Administration (FDA) as part of the biologics license application (BLA) for MYL-1401O last month.

The full study, "Effect of a Proposed Trastuzumab Biosimilar Compared With Trastuzumab on Overall Response Rate in Patients With ERBB2 (HER2)-Positive Metastatic Breast Cancer: A Randomized Clinical Trial," can be accessed on JAMA's website: http://jamanetwork.com/journals/jama/fullarticle/2590051.

Dr. Rugo is an independent consultant for Mylan. She serves as the Chair of the Steering Committee for the HERITAGE

Study and does not receive compensation from Mylan.

About the HERITAGE 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 safety and progression free survival, overall survival at 48 weeks. 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 within the equivalence margin (0.81, 1.24).

About the Biocon and Mylan Partnership
Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. 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 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 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 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 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 Statements: Mylan
This press release includes statements that constitute "forward-looking statements," including with regard to proposed biosimilar trastuzumab's potential to provide an effective treatment option for metastatic breast cancer patients; approval and cost of proposed biosimilar trastuzumab; Mylan's partnership with Biocon; and expanding patient access across the globe to this medicine as well as Mylan's broad portfolio of 15 additional biologics and insulin analogs currently in 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 Statements: 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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