Mylan and Biocon to Present Phase 3 Trastuzumab Biosimilar Data at the American Society of Clinical Oncology (ASCO) Annual Meeting

HERITAGE Study Shows Comparable Efficacy, Safety and Immunogenicity to Branded Trastuzumab in HER2-Positive Metastatic Breast Cancer Patients

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India – June 3, 2016 – Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced the presentation of data from the HERITAGE study at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 3-7. The study confirmed the efficacy, safety and immunogenicity of MYL-1401O, the proposed biosimilar trastuzumab co-developed by Biocon and Mylan, in comparison to branded trastuzumab.

“As one of the first companies in the industry to successfully complete a confirmatory efficacy and safety study comparing a proposed biosimilar to a branded cancer drug, this is a significant milestone for Mylan’s biosimilar program,” Mylan President Rajiv Malik said. “There is an urgent, unmet need for more affordable versions of biologic products and through our collaboration with Biocon we are well-positioned to be at the forefront to help deliver these complex products to patients around the world. We’re pleased that ASCO has recognized the importance of biosimilars in advancing cancer care and the significant role they will play in providing patients greater access to affordable treatment.”

Kiran Mazumdar Shaw, Chairperson and Managing Director, Biocon, added: “The positive outcomes of the global Phase 3 clinical study with our proposed biosimilar trastuzumab for HER2-positive breast cancer patients are a significant milestone in our joint biosimilars development program with Mylan. The trial will enable regulatory filings of our product in the developed markets. Biocon remains committed to develop affordable biologics and these study results will help us in enhancing access for cancer patients, caregivers and healthcare systems across the globe.”

Worldwide, nearly 2 million women are diagnosed with breast cancer each year, making it the second most common cancer in the world. HER2-positive metastatic 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 HER2-positive metastatic breast cancer patients. It is also indicated for adjuvant treatment of HER2 overexpressing breast cancer and metastatic gastric cancer. It is a targeted therapy that interferes with the HER2 protein and impedes cancer cell growth.

“The HERITAGE study successfully met the predefined endpoints of response equivalency. We are proud of this international collaboration which puts us one step closer to approval of this proposed biosimilar. The response rates at 24 weeks were 69.6% with MYL-1401O combined with taxane chemotherapy versus 64% with branded trastuzumab combined with the same chemotherapy agent. The ratio of overall response and difference in overall response fell within a narrow, pre-defined equivalence margin suggesting equal efficacy of both products. Safety was comparable between treatment groups. The rates of serious adverse events were 38% with MYL-1401O and 36% with branded trastuzumab, and there was no difference in cardiac safety,” commented lead study author Dr. Hope S. Rugo, professor of Medicine at the University of California, San Francisco.

Details of the sessions as on the ASCO website are as follows:

- ***“Abstract 583: A pharmacokinetics (PK) bioequivalence trial of proposed trastuzumab biosimilar Myl-1401O (A) vs EU-Herceptin® (B) and US-Herceptin® (C)”***
    - June 5, 8-11 a.m. CDT (Poster Session)
    - Poster #71
    - Presenter: Cornelius F. Waller, MD, University of Freiburg Medical Center
    - Location: Hall A
    - Link to abstract on the ASCO website: http://meetinglibrary.asco.org/content/163653-176

- ***“Abstract LBA503: HERITAGE: A phase III safety and efficacy trial of the proposed trastuzumab biosimilar Myl-1401O versus Herceptin®”***
    - June 6, 2:15-2:27 p.m. CDT (Oral Abstract Session)
    - Presenter: Hope S. Rugo, MD, University of California, San Francisco
    - Location: Hall D1
    - Link to abstract on the ASCO website: http://meetinglibrary.asco.org/content/162159-176

The abstract for the HERITAGE study has also been selected for the Best of ASCO® program this summer which will include several meetings across the globe.

Full session details and abstracts for the 2016 Annual Meeting can be found on the ASCO website at am.asco.org.

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 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 within the equivalence margin (0.81, 1.24).

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 the Mylan and Biocon Collaboration

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 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 nearly 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 Mylan being well-positioned though its collaboration with Biocon to be at the forefront to help deliver complex biosimilars to patients around the world, the significant role biosimilars will play in providing patients greater access to affordable treatment and regulatory filings. 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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