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FDA Oncologic Drugs Advisory Committee Unanimously Recommends Approval of Mylan and Biocon's Proposed Biosimilar Trastuzumab

Vote Marks First Proposed Biosimilar Trastuzumab to be Recommended by the Committee

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, July 13, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) recommended approval of the companies' proposed biosimilar trastuzumab. The committee voted 16-0 in support of eligible indications of the reference product, Herceptin®, which include HER2-positive breast cancer in the metastatic and adjuvant settings.



Mylan President Rajiv Malik commented: "We are pleased with ODAC's recommendation to support the approval of Mylan's proposed biosimilar trastuzumab to increase affordability, competition and most importantly overall access and use. As one of the largest suppliers of cancer medicines by volume in the U.S., Mylan is committed to serving this important patient community. We look forward to working with FDA to further increase access to this important treatment option for the thousands of patients affected by HER2-positive breast cancer each year."

Biocon CEO and Joint Managing Director Dr. Arun Chandavarkar said: "We welcome ODAC's endorsement of our biosimilar trastuzumab as it brings our collaboration a step closer to addressing the critical needs of cancer patients in the U.S. We now look forward to engaging with the FDA to seek final approval in order to expand access to a high-quality, affordable option for treating HER2-positive breast cancers."

Data presented to ODAC included results from analytical, nonclinical and clinical studies which demonstrated that our proposed biosimilar trastuzumab is highly similar to Herceptin, in line with the FDA assessment provided in the pre-meeting briefing documents. ODAC determined that no clinically meaningful differences exist between the biosimilar product and Herceptin in terms of safety, purity and potency. As such, the committee concluded that the totality of evidence supports a recommendation for FDA approval.

FDA uses advisory committees and panels to obtain independent expert advice on a variety of matters, including product approvals. FDA often follows the advice of ODAC in determining whether a product should come to market, although they are not required to follow it.

Mylan and Biocon's proposed biosimilar trastuzumab also is under review by regulatory authorities in Australia, Canada, Europe and several emerging markets.

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 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 ability of the proposed biosimilar trastuzumab to increase affordability, competition, and access for patients, and the companies' intention to seek final approval from FDA. 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, India 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

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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