January 11, 2017

# U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Trastuzumab

## If Approved, MYL-1401O Has Potential To Be the First Biosimilar Trastuzumab in the U.S.

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India, Jan. 11, 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) has accepted Mylan's biologics license application (BLA) for MYL-1401O, a proposed biosimilar trastuzumab, for filing through the 351(k) pathway. This product is a proposed biosimilar to branded trastuzumab, which is indicated to treat certain HER2-positive breast cancers. The anticipated FDA goal date set under the Biosimilar User Fee Act (BsUFA) is Sept. 3, 2017.

Seeing is believing™

**Mylan President Rajiv Malik commented**: "The FDA acceptance of our BLA for proposed biosimilar trastuzumab marks an important step toward increasing access to this treatment option for patients in the U.S. We believe that our comprehensive package of analytical similarity, non-clinical and clinical data submitted with the BLA will demonstrate similarity of the proposed biosimilar trastuzumab to the reference product. We are committed to bringing this product to market and look forward to working with FDA over the next months. This is Mylan and Biocon's first U.S. regulatory submission through the 351(k) pathway and reinforces the strength of our collaboration to increase access to a broad portfolio of high-quality, affordable biosimilars worldwide."

**Dr. Arun Chandavarkar, CEO and Joint Managing Director, Biocon, said**: "We are delighted by the FDA's acceptance of the BLA for our proposed biosimilar trastuzumab. It is a major milestone for the Mylan and Biocon collaboration since it is the first U.S. regulatory submission through our joint global biosimilars program. This development positions Biocon and Mylan among the first companies to be able to address the critical need of U.S. patients for a high-quality biosimilar to treat certain HER2-positive breast cancers in the near future."

Mylan and Biocon's proposed biosimilar trastuzumab is also under review by the European Medicines Agency (EMA).

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.

### 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 MYL-1401O, if approved, having the potential to be the first biosimilar trastuzumab in the U.S.; the anticipated FDA action date; steps to increase access to treatment options for patients in the U.S.; Mylan's belief that the comprehensive package of analytical similarity, non-clinical and clinical data submitted with the BLA will demonstrate similarity of the proposed biosimilar trastuzumab to the reference product; Mylan's commitment to bringing the product to market; the strength of Mylan and Biocon's collaboration to increase access to a broad portfolio of high-quality, affordable biosimilars worldwide; and the acceptance positioning Biocon and Mylan among the first companies to be able to address the critical need of U.S. patients for a high-quality biosimilar to treat certain HER2-positive breast cancers, in the near future. 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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