Press Release

Biocon and Mylan Announce Positive CHMP Opinion for Ogivri®, Biosimilar Trastuzumab

BENGALURU, India and HERTFORDSHIRE, England/PITTSBURGH Oct 19, 2018 -- Biocon Ltd. (BSE code: 532523, NSE: BIOCON) and Mylan N.V. (NASDAQ: MYL) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Ogivri®, a biosimilar to Roche's Herceptin® (trastuzumab).

The positive CHMP opinion is based on data submitted as part of the Marketing Authorization Application which included similarity assessment in analytical testing, preclinical and clinical studies. Results demonstrated no clinically meaningful differences in quality, potency and safety; therefore, establishing biosimilarity to the reference product, Herceptin. In addition, the Phase III clinical study (Heritage) demonstrated no clinically meaningful differences in terms of safety, efficacy and immunogenicity when compared to Herceptin in metastatic breast cancer patients, further reinforcing the highly similar nature of Ogivri.

The CHMP positive opinion will now be considered by the European Commission. The decision on approval is expected by the end of 2018.

Ogivri is indicated for treatment of patients with HER2 positive early breast cancer (EBC), metastatic breast cancer (MBC) and metastatic gastric cancer (MGC). Under supervision of the relevant healthcare professional it can be prescribed as either monotherapy or in combination with other medicines dependent on the relevant diagnosis.

Dr Arun Chandavarkar, **CEO and Joint Managing Director**, **Biocon** said: "CHMP's positive opinion on Biocon and Mylan's biosimilar Trastuzumab is yet another endorsement of our ability to develop and manufacture complex biosimilars for the benefit of patients globally. This is the third molecule from our collaboration portfolio to receive positive opinion from the European CHMP. We shall continue to execute on our biosimilars strategy of expanding affordable access to high quality products targeting critical illnesses like cancer."

Mylan President Rajiv Malik commented: "Obtaining positive CHMP opinion for Ogivri is another significant achievement in Mylan's continued efforts to bring more affordable medicines to the market. The strong science and technology program behind this product has been instrumental in achieving this milestone and moving us one step closer to providing patients with this alternative option. Mylan has a comprehensive and diverse biosimilars portfolio, and we are dedicated to bringing these complex medicines to market around the world."

Herceptin had brand sales of approximately $1.9 billion in Europe for the 12 months ending July 31, 2018, according to IQVIA.

Ogivri was approved by the U.S. Food and Drug Administration (FDA) in 2017 and is the first FDA-approved biosimilar for Herceptin in the U.S. Additional regulatory approvals have been secured in 35 countries around the world.

About Trastuzumab

Biological agents, including monoclonal antibodies, have increased the treatment options and improved outcomes for a number of cancers. Trastuzumab combined with chemotherapy has improved response, progression-free survival (PFS) and overall survival for ERBB2 (formerly human epidermal growth factor receptor 2 [HER2] or HER2/neu)–positive metastatic breast cancer and improved survival in early-stage ERBB2 positive breast cancer and metastatic ERBB2-positivegastric cancer compared with chemotherapy alone.

About the Biocon and Mylan Partnership

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Ogivri is one of 11 biologic and insulin products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the product 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 Biocon

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is a fully-integrated, innovation-led global biopharmaceutical company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and taken differentiated Small Molecules, Novel Biologics and a range of Biosimilars (Monoclonal Antibodies, rh Insulin and Insulin Glargine) from 'Lab to Market' in India, key emerging and developed markets. It has a large portfolio of biosimilars under clinical development with three of these approved in developed markets of US, EU, Japan and Australia. Its Novel pipeline includes promising assets like Insulin Tregopil, anti-CD6 antibody and a fusion protein for immuno-oncology. Some of its key brands are INSUGEN® (rh-insulin), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab) and ALZUMAb™ (Itolizumab). Follow-us on Twitter: @bioconlimited and visit www.biocon.com for more information.

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 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally 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. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed

or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, 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 and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements", including with regard to: the outcome of clinical studies; and that the decision on approval is expected by the end of 2018. 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: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; 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.

Contacts:

MYLAN
Christine Waller (Media)
724.514.1968
Email: communications@mylan.com

Melissa Trombetta (Investors)
724.514.1813
Email: InvestorRelations@mylan.com

BIOCON
Seema Ahuja (Media)
+91-80-2808-2222, M:+919972317792
Email:seema.ahuja@biocon.com

Saurabh Paliwal (Investors)
+91 80 6775 2040; M:+91 95383 80801
Email: investor.relations@biocon.com