December 1, 2017

U.S. FDA Approves Mylan and Biocon's Ogivri™, the First Biosimilar for Trastuzumab, for the Treatment of HER2-Positive Breast and Gastric Cancers

Mylan anticipates potentially being the first company to provide patient access to a biosimilar to Herceptin®, representing a significant milestone for Mylan, Biocon and the overall healthcare system
The FDA approval of Ogivri further demonstrates Mylan and Biocon's robust scientific capabilities in developing complex products
Ogivri is part of Mylan's robust portfolio of 16 biosimilar and insulin analog products, one of the largest and most diverse

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India, Dec. 1, 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 approved Mylan's Ogivri™ (trastuzumab-dkst), a biosimilar to Herceptin® (trastuzumab), co-developed with Biocon. Ogivri has been approved for all indications included in the label of the reference product, Herceptin, including for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). (1)

Ogivri is the first FDA-approved biosimilar to Herceptin and the first biosimilar from Mylan and Biocon's joint portfolio approved in the U.S. Mylan anticipates potentially being the first company to offer a biosimilar to Herceptin, as a result of Mylan's ability to secure global licenses for its trastuzumab product from Genentech and Roche earlier this year. This milestone secured a clear pathway to commercialize Mylan's biosimilar to Herceptin in various markets globally.

Mylan is a global leader in the development and manufacturing of complex products, including biosimilar medicines, with a portfolio of 16 biosimilar and insulin analog products - one of the industry's largest and most diverse portfolios.

Mylan CEO Heather Bresch commented: "The approval of Ogivri represents a monumental achievement for Mylan to increase patient access to biosimilars and deliver significant savings to the U.S. healthcare system. It will allow us to bring this important biosimilar - the first of its kind - to market in the U.S., expanding cancer-patient access to more affordable treatment. As one of the nation's leading suppliers of cancer medicines, Mylan is excited to add to our portfolio a product representing *a new generation of targeted therapies that have radically changed the way the disease is treated. Ogivri is one of many biosimilars in our robust pipeline that we look forward to introducing in the coming years as part of our ongoing commitment to increasing access to important medicines for patients."*

Mylan President Rajiv Malik added: "We are proud to receive FDA approval of Ogivri, a biosimilar to Herceptin, as this further underscores the strength of our science team and our ability to execute science programs for hard-to-make and complex products like biosimilars. Bringing such complex products to the market not only requires sound and robust science and a talented research and development team, but also the ability to manage legal and regulatory complexities and invest

significantly in manufacturing capabilities.

"This latest approval, among our other many accomplishments around the globe, not only continues to highlight Mylan's ability to differentiate itself from its peers, but also underscores why we have become a preferred partner of choice."

Kiran Mazumdar-Shaw, CMD Biocon, said: "The U.S. FDA's approval for our biosimilar trastuzumab is indeed a crowning moment that puts us in an exclusive league of global biosimilar players. It strengthens our resolve to focus on developing affordable biologics that can make cancer care both more effective and more equitable around the world. It is an important milestone in our journey of developing advanced therapies that have the potential to benefit billions of patients.

"Biocon and Mylan have a shared commitment to enhance access to cutting-edge bio-therapeutics and this approval will enable us to provide an affordable alternative for cancer care that will address the unmet needs of patients in the U.S."

Dr. Arun Chandavarkar, CEO & Joint MD, Biocon, added: "This approval represents a landmark achievement for the Biocon-Mylan collaboration and is an important endorsement of our development and manufacturing capabilities in the area of monoclonal antibodies. I sincerely acknowledge the contribution of every member of our teams who made this happen. This is the first biosimilar trastuzumab to be approved by the U.S. FDA and opens the door to a high quality, more affordable option for the treatment of eligible cancer patients in the U.S."

FDA approval was based on robust data from structural and functional characterization using multiple orthogonal techniques, nonclinical studies and pharmacokinetic evaluation in healthy subjects and patients and a safety, efficacy and immunogenicity study in relevant patient populations, which compared Ogivri to Herceptin. The data demonstrated that Ogivri is highly similar to Herceptin and no clinically meaningful differences exist between the biosimilar product and Herceptin in terms of safety, purity and potency. The FDA's decision follows the unanimous vote by the FDA Oncologic Drugs Advisory Committee (ODAC) in July 2017 recommending approval of Mylan's biosimilar to Herceptin.

Mylan and Biocon's biosimilar for Herceptin also is under review by regulatory authorities in Australia, Canada, Europe and several additional markets. It is already approved in 19 countries around the world, including India, thus providing increased access to this more affordable biologic for cancer patients.

In the U.S., an estimated 250,000 new cases of female breast cancer and 28,000 new cases of stomach cancer are expected to be diagnosed in 2017 alone. Approximately 20% to 25% of primary breast cancers are HER2-positive. Herceptin had U.S. sales of more than $2 billion for the 12 months ending Sept. 30, 2017, according to IQVIA.

Mylan is dedicated to supporting patients at every stage of cancer care with approximately 40 oncology supportive care, therapeutic and diagnostic products in the U.S.

(1) Ogivri may cause cardiomyopathy, infusion reactions, embryo-fetal toxicity and pulmonary toxicity.

- Cardiomyopathy: Ogivri can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue Herceptin for cardiomyopathy.
- Infusion Reactions, Pulmonary Toxicity: Discontinue Herceptin for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.
- Embryo-Fetal Toxicity: Exposure to Herceptin during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception.

Bringing Access to Biologics
Biologic drugs, like Herceptin, represent a large and increasing portion of the overall prescription drug market. They are important in the fight against many chronic and life-threatening diseases, including cancer. However, these drugs can cost far more than traditional prescription drugs, and their cost can prohibit access. For example, more than 20% of cancer patients skipped recommended treatments due to high out-of-pocket expenses. Biologics accounted for 70% of drug spending growth between 2010 and 2015.

Biosimilar medicines are deemed by FDA to be highly similar to an already-approved biologic product. They fill an urgent and unmet need for more affordable alternatives to biologic therapies, increasing access and providing savings for patients and the overall healthcare system. It is projected that biosimilars will generate a savings of $54 billion in direct spending on biologic drugs in the U.S. between 2017 and 2026.

About the Biocon and Mylan Partnership
Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar for Herceptin

is one of the six biologic 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 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.

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, 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), KRABEVA ® (Bevacizumab) 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.

Forward-Looking Statements: Mylan
This press release includes statements that constitute "forward-looking statements," including with regard to Mylan anticipating potentially being the first company to offer a biosimilar to Herceptin, as a result of Mylan's ability to secure global licenses for its trastuzumab product from Genentech and Roche earlier this year; this milestone securing a clear pathway to commercialize Mylan's biosimilar to Herceptin in various markets globally; the approval increasing patient access to biosimilars and delivering significant savings to the U.S. healthcare system; the approval allowing Mylan to bring this important biosimilar - the first of its kind - to market in the U.S., expanding cancer-patient access to more affordable treatment; Ogivri being one of many biosimilars in Mylan's robust pipeline that we look looking forward to introducing in the coming years as part of our ongoing commitment to increasing access to important medicines for patients; and the approval further underscoring Mylan's strength and ability to execute the science programs for hard-to-make and complex products like biosimilars.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
This Press Release may include forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. The statements - written and oral - that we periodically make contain forward looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify such statements by using words such as 'anticipates', 'estimates', 'expects', 'projects', 'intends', 'plans', 'believes' and words of similar substance in connection with any discussion of future performance. The market data & rankings used, are based on several published reports and internal company assessment. We cannot guarantee that these forward- looking statements will be realized, although we believe we have been prudent in our assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should bear this in mind. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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