Mylan and Biocon Launch Trastuzumab Biosimilar, Ogivri™ (trastuzumab-dkst), in the U.S.

December 2, 2019

This FDA-approved product, co-developed by Mylan and Biocon Biologics, was unanimously recommended by the FDA Oncologic Drugs Advisory Committee

Mylan to offer Ogivri in both the 420mg and 150mg strengths, increasing access to treatment for thousands of HER2-positive breast and gastric cancer patients

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India, Dec. 2, 2019 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced the U.S. launch of Ogivri™ (trastuzumab-dkst), a biosimilar to Herceptin® (trastuzumab). Ogivri is available in a 420mg multi-dose vial and a 150mg single-dose vial in order to provide patient dosing and treatment flexibility. Ogivri was the first biosimilar trastuzumab approved by the U.S. Food and Drug Administration (FDA) and unanimously recommended by the FDA Oncologic Drugs Advisory Committee (ODAC). Ogivri is approved for all indications of Herceptin including for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). Trastuzumab and biosimilar trastuzumab products contain a Boxed Warning for cardiomyopathy, infusion reactions, pulmonary toxicity and embryo-fetal toxicity.

Two supplemental Biologics License Applications were recently approved by the FDA, expanding the manufacturing capability for Ogivri, as well as Mylan and Biocon's first U.S. biosimilar, Fulphila®, a biosimilar to Neulasta®. Mylan and Biocon Biologics have sufficient manufacturing capacity to fulfil demand in the U.S. and global markets for both products.

Mylan President Rajiv Malik commented: "As one of the largest suppliers of oncology medicines in the U.S., we are proud to offer Ogivri, biosimilar trastuzumab, in both the 420mg and 150mg strengths and **help increase more affordable access to this important treatment option for breast and gastric cancer patients.** With regulatory approval for our biosimilar trastuzumab in more than 80 countries worldwide, we are bringing vast global biosimilars experience to the U.S. and look forward to continuing our work with all stakeholders in the healthcare system to reduce costs, improve access and advance care. With Ogivri, Fulphila and our generic oncology portfolio, Mylan is uniquely positioned to provide a broad range of treatment options for oncology patients.

Malik continued, "Today's launch has been achieved through years of hard work as a result of our successful collaboration with Biocon. Our early settlement and license with Roche to bring this product to market allows us to launch Ogivri without legal risk."

Dr. Christiane Hamacher, CEO, Biocon Biologics, said: "The U.S. launch of Ogivri, the biosimilar trastuzumab co-developed by Biocon Biologics and Mylan, marks a significant milestone in our biosimilars journey. It is an important endorsement of our science, development and manufacturing capabilities in the area of monoclonal antibodies. The introduction of both 420mg multi-use vials and 150mg single-use vials of a high quality biosimilar trastuzumab with robust long-term efficacy and safety data will offer greater choice and value to patients, prescribers and payors in the U.S. As a global frontrunner in biosimilars, Biocon Biologics is committed to fulfil unmet patient needs by providing greater affordability for enhanced patient access. We aspire to serve 5 million patients through our biosimilars portfolio and cross a revenue milestone of US$ 1bn by FY22.

"Ogivri is the second biosimilar from our partnered portfolio being commercialized by Mylan in the U.S. Last year, through the launch of Fulphila we helped in expanding patient access to biosimilar pegfilgrastim," she added.

FDA approval of Ogivri was based on robust data demonstrating 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. Long-term results of the landmark HERITAGE study including overall survival data at 36 months were presented at this year's American Society of Clinical Oncology (ASCO) Annual Meeting.

Dr. Hope S. Rugo, professor of medicine at the University of California, San Francisco, and lead author of the HERITAGE study commented: "Trastuzumab-dkst (Ogivri) has many firsts to its credit. It was one of the first biosimilar oncology products to get a unanimous approval vote at an ODAC meeting, and it was the first biosimilar study to be published in the Journal of the American Medical Association. In this context, the HERITAGE study had a unique trial design that not only evaluated objective response rate at week 24 as its primary endpoint but also assessed key endpoints including progression-free survival rate and overall survival at 36 months. The concordant efficacy data across all three endpoints conclusively demonstrated that Ogivri was similar to Herceptin, and patients without progression now continue on Ogivri as maintenance therapy. We are pleased that patients with HER2-positive cancers now have an additional treatment option backed by robust safety and efficacy data, including long-term 36-month data. The worldwide introduction of this agent has already improved access to trastuzumab."

Ogivri is the second biosimilar to be offered by Mylan through the Mylan-Biocon Biologics partnership in the U.S. and the second FDA-approved biosimilar through this collaboration to support cancer patients. Mylan and Biocon launched the world's first biosimilar trastuzumab in India in 2014. Today, Mylan has one of the largest and most diverse biosimilars portfolios, with 20 biosimilar and insulin analog products in development or on the market.

A full suite of patient services for Ogivri will be offered through the Mylan Advocate program.

About the HERITAGE Study

HERITAGE is a double-blind, randomized clinical trial designed to evaluate comparative efficacy and safety of the trastuzumab biosimilar trastuzumab-dkst (formerly known as 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 trastuzumab-dkst 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 trastuzumab-dkst versus branded trastuzumab, defined as a 90% confidence interval for the ratio of best overall response within the equivalence margin (0.81, 1.24).The primary endpoint has previously been reported: the overall response rate in patients with HER2-positive metastatic breast cancer at week 24 was equivalent between the trastuzumab-dkst and trastuzumab groups (Rugo et al. *JAMA*. 2017;317:37-47).

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 treatment of many chronic and acute diseases, including cancer. However, these drugs can cost far more than traditional prescription drugs, and their cost can prohibit access. One study found that nearly 40% of women were at least somewhat worried about finances because of their breast cancer treatment. Biologics now account for about 40% of all U.S. drug spending and 70% of spending growth from 2010 to 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's estimated that the introduction of biosimilars in the U.S. could save the nation's healthcare system up to $150 billion between 2017 and 2027.

Ogivri will be launched at a competitive discount for customers to help ensure access and increase treatment options for patients.

About the Biocon and Mylan Partnership

Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar trastuzumab is one of the 11 biologic products being 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 approximately 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 Limited

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as generic formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. www.biocon.com Follow-us on Twitter: @bioconlimited

Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company's portfolio of biosimilar molecules, comprises a rich pipeline of approved and in-development biosimilars which are an outcome of its high end R&D and global scale manufacturing expertise. The Company has commercialized three of its biosimilars in the developed markets like EU, U.S., Japan and Australia. It is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. Follow-us on Twitter: @BioconBiologics

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to that Mylan and Biocon Biologics have sufficient manufacturing capacity to fulfil demand in the U.S. and global markets for Ogivri and Fulphila; that Mylan and Biocon look forward to continuing our work with all stakeholders in the healthcare system to reduce costs, improve access and advance care; that the product is brought to market without legal risk; and that the introduction of biosimilars in the U.S. could save the nation's healthcare system up to $150 billion. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; 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; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; 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 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.

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SOURCE Mylan N.V.

MYLAN Christine Waller (Media), 724.514.1968, Email: communications@mylan.com, Melissa Trombetta (Investors), 724.514.1813, Email: InvestorRelations@mylan.com, or BIOCON, Seema Ahuja (Media), +91-80-2808-2222, M:+919972317792, Email: seema.ahuja@biocon.com, Saurabh Paliwal (Investors), +91 80 6775 2040, Email: investor.relations@biocon.com