Abstract #1021

Press Release

Biocon and Mylan to Present Final Overall Survival Data for Ogivri™ (trastuzumab-dkst), a biosimilar to Herceptin®, at the American Society of Clinical Oncology (ASCO) Annual Meeting

Ogivri™ is the first biosimilar for Herceptin® approved by the U.S. Food and Drug Administration (FDA) for all indications including HER2-positive breast and gastric cancers

HERTFORDSHIRE, England, PITTSBURGH; BENGALURU, India, – May 15/16, 2019 –

Mylan N.V. (NASDAQ: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that final data from the HERITAGE study will be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The HERITAGE study compared Ogivri™ to the reference product, Herceptin®, in patients with HER2+ metastatic breast cancer in combination with taxanes for the first 24 weeks and then as a monotherapy until progression. Safety and overall survival, cumulative through 36 months of follow-up, will be presented as part of the Breast Cancer - Metastatic session, "HER2-Positive Disease: How Far Have We Come?," on June 2.

Christiane Hamacher, CEO, Biocon Biologics, said: *"The final safety and overall survival data from the HERITAGE study for our biosimilar trastuzumab, Ogivri, cumulative through 36 months of follow up, reconfirms that efficacy and safety is very similar to the reference product, Herceptin. The presentation of this data at ASCO will enable a wider adoption of our biosimilar trastuzumab which has so far benefited thousands of patients across the globe. Biocon Biologics is committed to enable access to this high quality affordable therapy for HER2-positive breast and gastric cancer patients as we strive to co-create a healthy future.*"

Mylan Head of Global Biologics, R&D, Arnd Annweiler, commented: *"We're pleased with the final results of the landmark HERITAGE study which further validate the safety and efficacy profile of Ogivri and confirm that no clinically meaningful differences exist between the biosimilar product and Herceptin in terms of safety, purity and potency. We have long been committed to the science and clinical data behind this important treatment and are proud to reach this milestone. Today, we continue on our mission to increase access to Ogivri and the additional biosimilars in our pipeline for patients around the world. We're grateful for ASCO's recognition of this critical study over the past years and the important role they have played in educating and*

instilling confidence in healthcare providers and patients about the safety, efficacy and value of biosimilars."

Following are the session details:

- ***Abstract 1021: Biosimilar trastuzumab-dkst monotherapy versus trastuzumab monotherapy after combination therapy: Final overall survival (OS) from the phase III HERITAGE Trial***

    - Date: June 2, 2019
    - Poster display: #102, 8-11 a.m. CDT, Hall A
    - Poster discussion: 11:15 a.m.-12:45 p.m. CDT, Hall D2
    - Session: Breast Cancer – Metastatic
    - Presenter: Dr. Cornelius Waller, Department of Haematology, Oncology and Stem Cell Transplantation, University Medical Centre Freiburg and Faculty of Medicine, University of Freiburg, Freiburg, Germany

Mylan and Biocon's biosimilar for Herceptin has received regulatory approval in more than 65 countries worldwide.

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).

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 a fully-integrated, innovation-led global biopharmaceutical company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. The Company has developed and commercialized a range of Biosimilars (Monoclonal Antibodies, Pegfilgrastim, rh- Insulin and Insulin Glargine), Novel Biologics and differentiated Small Molecules and Generic Formulations in India and Key emerging markets. It has a large portfolio of biosimilars under global clinical development with three of these commercialized in the developed markets of EU, U.S. and Japan. It has promising novel assets in immunotherapy under development. Some of its key brands are INSUGEN® (rh-insulin), Basalog (insulin glargine), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab)
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Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to the outcome of clinical trials. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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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