Mylan and Biocon to Present New Data at the American Society of Clinical Oncology (ASCO) Annual Meeting Reinforcing the Efficacy, Safety and Immunogenicity of Ogivri™, the first biosimilar for Herceptin® approved by FDA

June 1, 2018

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, June 1, 2018 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that 48-week results from the HERITAGE study will be presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 1-5. The HERITAGE study compared Ogivri ™, the first biosimilar for Herceptin® approved in the U.S., to the reference product in patients with metastatic breast cancer in combination with taxanes for the first 24 weeks and then as a monotherapy until progression. Data obtained after 48 weeks of treatment will be included as part of the Clinical Science Symposium titled, "The Arrival of Biosimilars," on June 4.

Mylan's Head of Global Biologics, R&D, Arnd Annweiler, commented: "We continue to be pleased with the progress of the HERITAGE study, which helped to support the recent FDA approval of Ogivri, the first biosimilar for Herceptin in the U.S. The 48-week data further demonstrate 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. We applaud ASCO for continuing to support biosimilar development and recognizing the need for more affordable treatment options for cancer patients."

Dr. Narendra Chirmule, Sr. Vice President & Head of R&D at Biocon, said: "We are extremely pleased to present the 48-week additional data from the HERITAGE study at ASCO, which further demonstrate that our biosimilar trastuzumab, Ogivri, does not have any clinically meaningful differences in terms of safety, purity and potency in comparison to the reference product, Herceptin. We believe this positive data will enable wider adoption of our biosimilar trastuzumab, thus expanding access to this therapy for HER2-positive metastatic breast and gastric cancer patients across the world."

Following are session details:

- ***Abstract 110: Biosimilar trastuzumab-dkst monotherapy versus trastuzumab monotherapy after combination therapy: Toxicity, efficacy, and immunogenicity from the phase 3 Heritage trial***
  - June 4, 2018, 9:45-11:15 a.m. CDT
  - Session: The Arrival of Biosimilars
  - Presenter: Hope S. Rugo, MD, University of California, San Francisco
  - Location: Hall D1
  - Link to abstract: http://abstracts.asco.org/214/AbstView_214_224369.html

In addition, data related to Mylan and Biocon's proposed biosimilar to Neulasta® (pegfilgrastim) were selected for publication in conjunction with the 2018 ASCO Annual Meeting.

Details are as follows:

- ***Abstract e19028: Characterization and similarity assessment of a pegfilgrastim biosimilar MYL-1401H.***
  - Link to abstract: http://abstracts.asco.org/214/AbstView_214_227973.html

More information about the 2018 Annual Meeting can be found on the ASCO website at am.asco.org.

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 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 Statement: 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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