U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Bevacizumab for Review

March 9, 2020

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, March 9, 2020 /PRNewswire/ -- **Mylan N.V.** (NASDAQ: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the U.S. Food and Drug Administration (FDA) has accepted Mylan's Biologics License Application (BLA) for MYL-1402O, a proposed biosimilar to Avastin® (bevacizumab), for review under the 351(k) pathway.

The BLA seeks approval of bevacizumab for first-line and second-line treatment of patients with metastatic colorectal cancer in combination with fluorouracil-based chemotherapy; first-line use for patients with non-squamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma in combination with interferon alfa; and persistent, recurrent or metastatic cervical cancer.

The FDA goal date set under the Biosimilar User Fee Act (BsUFA) is Dec. 27, 2020.

Mylan and Biocon's proposed biosimilar bevacizumab is expected to be the third biosimilar from the partnered portfolio for cancer patients in the U.S. It is currently available in India and other developing markets.

Mylan President Rajiv Malik commented: *"As we continue toward our goal of expanding access to cancer treatments for oncology patients, the FDA acceptance of our application for proposed biosimilar bevacizumab is another important step forward to increase competition, drive health system savings and expand our growing oncology portfolio to provide a broad range of offerings. We're encouraged by the results of our scientific program to date and look forward to advancing the review of our application."*

Dr Christiane Hamacher, CEO, Biocon Biologics, said: *"The US FDA's acceptance of our BLA for a proposed biosimilar bevacizumab co-developed by Biocon Biologics and Mylan is an important milepost in our journey of enabling access to affordable cancer therapies for patients. Once approved, our proposed biosimilar bevacizumab will provide an affordable alternative to the branded biologic for the approved indications. Biocon Biologics' strong R&D and manufacturing capabilities have enabled us to offer two key biosimilars to cancer patients in the U.S. and bevacizumab will further expand our oncology portfolio."*

The BLA is supported by a global randomized, controlled phase 3 clinical trial to evaluate the efficacy, safety and immunogenicity of proposed biosimilar bevacizumab versus Avastin. The study included patients diagnosed with stage 4 non-squamous non-small cell lung cancer. Eligible patients were randomised to receive either the proposed biosimilar bevacizumab or Avastin along with carboplatin and paclitaxel for up to six cycles (18 weeks). After which the patients continued to receive monotherapy until week 42. Additionally, patients benefitting from the treatment continued on bevacizumab monotherapy. The primary endpoint was overall response at week 18, using RECIST 1.1. Secondary endpoints included safety, progression free survival and overall survival at week 18 and 42.

A total of 671 patients were randomized. At week 18, the study met the primary endpoint and the 90% confidence interval for the best ORR (objective response rate) ratio was within the pre-specified equivalence margin. The safety which included immunogenicity was found to be similar to Avastin.

About the Biocon and Mylan Partnership
Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Our proposed biosimilar bevacizumab 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 the timing and outcome of clinical trials and regulatory review; the statement that the FDA acceptance of our application for proposed biosimilar bevacizumab is another important step forward to increase competition, drive health system savings and expand our growing oncology portfolio to provide a broad range of offerings; we are encouraged by the results of our scientific program to date and look forward to advancing the review of application; and once approved, our proposed biosimilar bevacizumab will provide an affordable alternative to branded bevacizumab (Avastin) for cancer patients for the approved indications. 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.

View original content to download multimedia:http://www.prnewswire.com/news-releases/us-fda-accepts-biologics-license-application-bla-for-mylan-and-biocons-proposed-biosimilar-bevacizumab-for-review-301019381.html

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; BIOCON, Seema Ahuja (Media), +91 80 2808 2222, M:+91 9972 317792, Email: seema.ahuja@biocon.com; Saurabh Paliwal (Investors), +91 80 6775 2040, Email: investor.relations@biocon.com