Mylan and Biocon Launch Fulphila®, Biosimilar Pegfilgrastim, in Canada

April 28, 2020

HERTFORDSHIRE, England, PITTSBURGH and BENGALURU, India, April 28, 2020 /CNW/ -- Mylan N.V. and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced the launch of Fulphila®, a biosimilar to Neulasta® (pegfilgrastim). Fulphila is approved by Health Canada to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs.

The approval of Fulphila was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that the product is highly similar to Neulasta and no clinically meaningful differences in terms of safety and efficacy exist.

Mylan Canada Country Manager David Simpson commented, "As a global leader in the development of complex products, including biosimilar medicines, Mylan is proud to launch Fulphila in Canada. We have reached a negotiated agreement with the Pan-Canadian Pharmaceutical Alliance (pCPA) to help expand access to treatment and reduce costs for cancer patients. Fulphila is the second biosimilar to be offered by Mylan through the Mylan-Biocon Biologics partnership in Canada and the second biosimilar approved by Health Canada through this collaboration to support cancer patients. With Mylan's global portfolio of 20 biosimilar and insulin analog products in development or on the market, we are bringing vast biosimilars experience to the market here in Canada. Among these products is an extensive oncology portfolio increasing choice and access for patients across the region."

Biocon Biologics, CEO, Dr Christiane Hamacher said, "We are pleased to expand access to our high quality biosimilar pegfilgrastim to patients in Canada, after a successful launch in the U.S. This is the second biosimilar from our portfolio to be launched in Canada by our partner Mylan and is an endorsement of our science, development and manufacturing capabilities in the area of biologics. We are committed to serve 5 million patients through our biosimilars portfolio and cross a revenue milestone of US$1bn by FY22."

A suite of patient services will be available at launch to further support patients and caregivers with treatment.

About the Biocon and Mylan Partnership

Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar pegfilgrastim 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 shared or 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 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 approximately 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 outcome of product launches. 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 the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; 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.



SOURCE Mylan N.V.