U.S. FDA Approves Mylan and Biocon's Fulphila™ (pegfilgrastim-jmdb), the First Biosimilar to Neulasta®

Fulphila is expected to be the first biosimilar pegfilgrastim available in the U.S. to help patients with nonmyeloid cancers reduce the risk of infection following myelosuppressive chemotherapy

Fulphila is the second FDA-approved biosimilar through the Mylan-Biocon collaboration, further demonstrating the companies' leadership and commitment to expanding patient access to critical biologic medicines

HERTFORDSHIRE, England/PITTSBURGH and BENGALURU, India, June 4-5, 2018 -- 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 approved Mylan's Fulphila™ (pegfilgrastim-jmbd), a biosimilar to Neulasta® (pegfilgrastim), co-developed with Biocon. Fulphila has been approved to reduce the duration of febrile neutropenia (fever or other signs of infection with a low count of neutrophils, a type of white blood cells) in patients treated with chemotherapy in certain types of cancer.

Fulphila is the first FDA-approved biosimilar to Neulasta and the second biosimilar from Mylan and Biocon's joint portfolio approved in the U.S. Mylan anticipates launching Fulphila in the coming weeks, representing the first alternative, more affordable treatment option to Neulasta for oncology patients. A suite of patient services also will be available at launch to further support patients and caregivers with treatment.

Mylan CEO Heather Bresch commented: "*I couldn't be prouder of this approval for Fulphila, the first alternative option for pegfilgrastim approved in the U.S., as it represents an important milestone for patients and further demonstrates Mylan's continued fight to expand access to medicine. FDA's approval of this product, as well as the agency's continued focus on biosimilars, mark crucial steps towards lowering treatment costs and providing alternative options for patients. As a leading supplier of cancer medicines in the U.S, Mylan is committed to offering affordable and accessible solutions for patients with cancer at every step of their journey. Enhancing access to treatment has always been our top priority and what we'll continue to deliver to the healthcare system in the U.S. and beyond*."

Mylan President Rajiv Malik added: "*Today's approval of Fulphila represents a meaningful step forward in the affordability and accessibility of cancer care in the U.S. It also is yet another confirmation of Mylan's deep scientific, clinical, regulatory and intellectual property capabilities, which are widely recognized in the industry and bolster Mylan's reputation as a partner of choice in the global effort to bring complex medicines to market. The approval of Fulphila, the first biosimilar to Neulasta, joins other recent examples such as the approval of Ogivri™, the first biosimilar to Herceptin®, in the growing portfolio of complex medicines that Mylan is making available for patients who need them. We're pleased to reach this important milestone in partnership with Biocon and proud of the progress of our biosimilars program. We look forward to launching Fulphila and continuing to increase access to more affordable treatments*."

As a global leader in the development and manufacturing of complex products, Mylan has a portfolio of 20 biosimilar and insulin analog products – one of the industry's largest and most diverse

portfolios – and deep experience with more than 60 marketing authorizations for biosimilar products worldwide.

Mylan was the first company to receive FDA approval of Ogivri[1], a biosimilar to Herceptin (trastuzumab), in late 2017 and has continued to obtain regulatory approvals for biosimilar trastuzumab in nearly 30 additional countries around the world.

Biocon CEO & Joint Managing Director, Dr. Arun Chandavarkar, said: "*It's a moment of great pride to be the first to receive approval for a biosimilar pegfilgrastim by the USFDA. This important milestone comes soon after our achievement of being the first to receive USFDA approval for biosimilar trastuzumab. It represents a further endorsement of the Biocon-Mylan partnership's ability to successfully develop complex molecules to exacting quality and regulatory standards. This approval expands our oncology portfolio for the benefit of cancer patients and supports our mission to improve access to high quality, affordable biopharmaceuticals globally.*"

The approval for Fulphila was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that the product is highly similar to Neulasta. The data demonstrated that there were no clinically meaningful differences between the biosimilar product and Neulasta in terms of safety, purity and potency.

Neulasta had U.S. sales of $4.2 billion for the 12 months ending March 31, 2018, according to IQVIA.

Fulphila is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Do not administer Fulphila to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. Splenic rupture and sickle cell crisis, including fatal cases, can occur following the administration of Fulphila. Discontinue Fulphila in patients with Acute Respiratory Distress Syndrome and consider dose reduction or interruption in patients with glomerulonephritis. The most common adverse reactions are bone pain and pain in extremity.

[1] *Ogivri is approved for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). It may cause cardiomyopathy, infusion reactions, embryo-fetal toxicity and pulmonary toxicity.*

- *Cardiomyopathy: Ogivri can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue Herceptin for cardiomyopathy.*
- *Infusion Reactions, Pulmonary Toxicity: Discontinue Herceptin for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.*
- *Embryo-Fetal Toxicity: Exposure to Herceptin during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception.*

Bringing Access to Biologics

Biologic drugs, like Neulasta, 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. According to a survey from the American Society for Clinical Oncology, more than half (56%) of respondents said they were very or somewhat concerned they could afford treatment. Biologics accounted for 70% of drug spending growth between 2010 and 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 is projected that biosimilars will generate a savings of $54 billion in direct spending on biologic drugs in the U.S. between 2017 and 2026.

About the Biocon and Mylan Partnership

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar to Neulasta is one of 11 biologic and insulin products 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 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 Statements: Mylan

This press release includes statements that constitute "forward-looking statements", including with regard to: the expected launch and marketing of Fulphila; Fulphila being expected to be the first biosimilar pegfilgrastim available in the U.S. to help patients with nonmyeloid cancers reduce the risk of infection following myelosuppressive chemotherapy; that Fulphila is the second FDA-approved biosimilar through the Mylan-Biocon collaboration, demonstrating the companies' leadership and commitment to expanding patient access to critical biologic medicine; Mylan anticipating launching Fulphila in the coming weeks, representing the first alternative, more affordable treatment option to Neulasta for oncology patients; a suite of patient services also being available at launch to further support patients and caregivers with treatment; FDA's approval of this product, as well as the agency's continued focus on biosimilars, marks a crucial step towards lowering treatment

costs and providing alternative options for patients; and that we look forward to launching Fulphila and continuing to increase access to more affordable treatments. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: that the partnership is subject to approval by the Israeli Innovation Authority; success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; 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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