



Mylan and Biocon Announce Positive CHMP Opinion for Fulphila®, Biosimilar Pegfilgrastim

September 21, 2018

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, Sept. 21, 2018 /PRNewswire/ -- [Mylan N.V.](#) (NASDAQ: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Fulphila®, a biosimilar to Amgen's Neulasta® (pegfilgrastim).

The CHMP positive opinion is based upon a review of evidence demonstrating biosimilarity. Data submitted as part of the Marketing Authorization Application included similarity assessment in analytical testing, preclinical and clinical studies that demonstrated biosimilarity to the reference product, Neulasta. The Phase I program in healthy volunteers and Phase III clinical study conducted in breast cancer patients receiving adjuvant and neoadjuvant chemotherapy demonstrated no clinically meaningful differences in terms of pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity compared to Neulasta.

The CHMP positive opinion will now be considered by the European Commission. The decision on approval is expected by November 2018.

Fulphila was approved by the U.S. Food and Drug Administration (FDA) earlier this year and is the first FDA-approved biosimilar for Neulasta in the U.S. Regulatory applications for Fulphila also have been submitted in Australia, New Zealand, Canada and several other countries.

Mylan President Rajiv Malik commented: "We are very proud to be a leader in bringing the first wave of biosimilars to the European market and driving greater access to more affordable treatment options for patients living with chronic and life-threatening illness such as cancer. Receiving CHMP positive opinion for our pegfilgrastim biosimilar, Fulphila, is a key milestone in this journey, demonstrating our commitment to patient and healthcare communities across Europe and the strength of our collaboration with Biocon."

Biocon CEO & Joint Managing Director, Dr. Arun Chandavarkar, said: "CHMP's decision to recommend approval of Biocon and Mylan's biosimilar Pegfilgrastim brings us a step closer to offer this high quality, affordable biologic therapy for cancer patients in the EU, having launched this product in the US, earlier this year. It is an outcome of our commitment to enhance access for patients and be a leading global biosimilars player on the back of significant investments in R&D and global scale manufacturing, together with our partner Mylan."

Neulasta had brand sales of more than \$450 million in Europe for the 12 months ending June 30, 2018, according to IQVIA.

About Pegfilgrastim

Chemotherapy-induced febrile neutropenia (FN) causes treatment delays and interruptions and can have fatal consequences. Current guidelines provide recommendations on granulocyte colony-stimulating factors (G-CSF) for prevention of FN when the risk is considered to be high. Pegfilgrastim as an injectable biologic medication is a PEGylated form of the recombinant human granulocyte colony-stimulating factor (G-CSF). It serves to stimulate the level of white blood cells (neutrophils). Pegfilgrastim treatment can be used to stimulate bone marrow to produce more neutrophils to fight infection in patients undergoing chemotherapy.

About Biosimilars

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. The European Medicines Agency (EMA) is responsible for evaluating the majority of applications to market biosimilars in the European Union (EU). Further information is available on the EMA website [here](#).

About the Biocon and Mylan Partnership

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Fulphila 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. For more information, visit our website: www.biocon.com or Follow us on twitter: @bioconlimited

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements", including with regard to the outcome of clinical studies; and the decision on approval being expected by November 2018. 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: 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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