PRESS RELEASE

USFDA Approves Biocon's sBLA for Pegfilgrastim New Manufacturing Facility

Expanded Capacity will Enable Greater Patient Access Globally

BENGALURU, India, Nov. 27, 2019

Biocon Ltd (BSE code: 532523, NSE: BIOCON) announced today that Biocon and Mylan's supplemental Biologics License Application (sBLA) for Pegfilgrastim Drug Substance to be manufactured at Biocon's new Biologics manufacturing facility has been approved by the U.S. Food and Drug Administration (FDA).

This additional approval of its new manufacturing facility for Pegfilgrastim in Bengaluru will enable Biocon Biologics, a subsidiary of Biocon Ltd, and Mylan to scale up capacity multi-fold and address the growing market opportunities in the U.S. and other global markets. The U.S. FDA had conducted a Pre-Approval Inspection of this new Drug Substance manufacturing facility from Sep 10 to Sep 19, 2019.

Biocon Biologics is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. It has been investing in expanding its manufacturing capacity in line with its expectations of higher biosimilars penetration in developed and emerging markets.

Dr. Christiane Hamacher, CEO, Biocon Biologics, said: *"We are extremely pleased with the U.S. FDA approval of our sBLA for Pegfilgrastim manufactured at our new Biologics Drug Substance facility. This is a significant milepost in our journey of serving 5 million patients by FY22 and crossing a revenue milestone of USD 1 billion. Biocon Biologics has been making continued investments in building global-scale, cost-competitive, complex manufacturing capabilities to address global market opportunities. This approval will help us better meet global patient needs for Fulphila®, a high quality biosimilar Pegfilgrastim co-developed with Mylan and manufactured by Biocon Biologics.*
"Continued penetration of biosimilars will enable higher cost savings for the U.S. healthcare system leading to expansion of patient access to high quality affordable biologics. We are committed to use our science, scale and expertise to shift the access paradigm for patients in need of biosimilars like Pegfilgrastim across the globe," she added.

Biocon Biologics, through its partner Mylan, has commercialized three of its co-developed biosimilars in developed markets like U.S., Canada, EU and Australia.

Fulphila®, a biosimilar Pegfilgrastim co-developed by Biocon and Mylan, was the first biosimilar Pegfilgrastim to be approved in the U.S. and was commercially launched in July 2018. It was one of the most successful biosimilar launches in the U.S.

With the approval of this additional facility, Biocon Biologics and Mylan will be able to address the growing needs of patients for biosimilar Pegfilgrastim in the U.S. where introduction of the biosimilar has expanded the overall market, increasing access for patients in the U.S., as well as in other global markets. Fulphila® is also approved in other developed markets of EU, Australia and Canada.

Biocon Biologics, which houses Biocon's biosimilars business, is committed to serve the needs of patients, people and partners by providing innovative affordable healthcare solutions going beyond the product. It aims to impact 2.6 million patient lives in FY 20 and aspires to position the company as a global leader.

About Biocon Biologics:

Biocon Biologics is a subsidiary of Biocon Ltd, an innovation led global biopharmaceuticals company. Biocon Biologics is engaged in developing high quality, affordable biosimilars aimed at expanding patient access to cutting-edge class of therapies across the world. It is uniquely positioned as a fully integrated 'pure play' biosimilars organization globally. Biocon Biologics aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company has a large portfolio of biosimilars under global clinical development with three of these commercialized in developed markets like U.S, EU, Australia and Japan. Biocon Biologics has a product pipeline of 28 molecules, including 11 partnered with Mylan, several with Sandoz and many being developed independently. Follow Biocon Biologics on twitter: @bioconbiologics

About Biocon Ltd:

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 is a leading global player for high quality biosimilars, APIs including statins, immunosuppressants and specialty molecules. Biocon 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 U.S. and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. Biocon is committed to pursue the path of innovation to develop products that have the potential to benefit a billion lives. For further information, please visit **www.biocon.com** follow Biocon Limited on Twitter @bioconlimited

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