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USFDA approves Biocon’s sBLA for Pegfilgrastim Bengaluru facility

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Expanded Capacity will enable greater patient access globally

Biocon Ltd has announced 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.