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USFDA nod to Biocon's new Bengaluru unit

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Biopharmaceutical major Biocon on Wednesday received approval from the US health regulator to manufacture biosimilar Pegfilgrastim at its new drug substance facility in Bengaluru. After standard operating procedures, the new unit will begin manufacturing immediately, a company spokesperson said.

The US Food and Drug Administration's (USFDA's) nod to Biocon's supplemental biologics licence application for the new unit will expand the company's capacity multifold, said the Bengaluru-headquartered firm.

"This is a significant milestone in our journey of serving five million patients by FY22 and crossing a revenue milestone of \$1 billion. 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," said Christiane Hamacher, chief executive officer, Biocon Biologics.

Fulphila was the first

biosimilar Pegfilgrastim to be approved in the US market and was commercially launched in July. The biosimilar helps patients with non-myeloid cancers and reduces the risk of infection following myelosuppressive chemotherapy.

With this additional facility, Biocon Biologics will be able to address the growing needs of the patients for Pegfilgrastim in the US where introduction of the biosimilar has expanded the overall market, as well as in European Union (EU), Canada, and Australia. Currently, Biocon Biologics has a product pipeline of 28 molecules, including 11 with Mylan, several with Sandoz while some being developed independently. It has commercialised three of its biosimilars in the US, EU, Australia, and Japan so far.

Biocon Chairperson and Managing Director Kiran Mazumdar-Shaw had recently made a personal commitment towards enabling universal access to high-quality rh-Insulin to patients in low- and middle-income countries at less than ₹7 per day through Biocon Biologics.