BioSpectrum the business of Bio & Health Sciences

Biocon’s Bengaluru Facility gets EIR from U.S. FDA

05 November 2019 | News

Reaffirms Biocon's Capability to Manufacture Biosimilars for Patients in U.S

Biocon Ltd, an innovation-led global biopharmaceuticals company, has received an Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) for its Biologics Drug Product facility in Bengaluru, stating the inspection is closed. This reaffirms Biocon Biologics’ global scale manufacturing capability for high quality, affordable biosimilars for the U.S. market.

Biocon had undergone a surveillance (routine) cGMP inspection of this Drug Product facility in Bengaluru from Aug 22 to Aug 30, 2019. The receipt of EIR indicates a successful closure of this inspection. Biocon is committed to highest standards of Quality and Compliance.

Dr Christiane Hamacher, CEO, Biocon Biologics said, “We are pleased to receive the EIR from the U.S. FDA for our large Biologics Drug Product facility in Bengaluru, which is a strong building block for our US$ 1 billion revenue target. The EIR for this facility reaffirms our manufacturing capabilities for high quality biosimilars to serve the needs of patients in the U.S. Through our partner Mylan we have U.S. FDA approvals for bPegfilgrastim and bTrastuzumab, and have been making a difference to cancer patients with bPegfilgrastim. We are confident of providing an affordable alternative with commercialization of bTrastuzumab soon, leading to tremendous cost savings to the U.S. healthcare system.”

The U.S. FDA in October had also approved Biocon’s new Drug Product (DP) filling line for biosimilar Trastuzumab 150 mg vials at the Biologics facility in Bengaluru, following a pre-approval Inspection (PAI) of the facility in September 2019.

Biocon Biologics is uniquely positioned as a fully integrated ‘pure play’ biosimilars organization in the world, committed to enable affordable access to patients across the globe. We are targeting to serve the needs of over 2.5 million patients in FY20. We aspire to serve nearly 5 million patients and cross revenues of US$ 1 billion by FY22, driven by the near term

commercialization of Trastuzumab and Insulin Glargine in the U.S., continual growth in existing developed and emerging markets and launch of Insulin Aspart and Bevacizumab in various global markets.

The Company, which has one of the broadest and deepest pipelines in the industry straddling insulins, monoclonal antibodies and other recombinant proteins, has core expertise in developing, manufacturing and commercializing high quality biosimilars.

Biocon Biologics has a product pipeline of 28 molecules, including 11 with Mylan, several with Sandoz, and is developing

many independently. The Company’s therapeutic basket includes molecules from diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases.

In August, Biocon's Malaysia Insulin Glargine manufacturing facility received the Certificate of GMP compliance from the European Medicines Agency, expanding its capacities multi-fold to serve the needs of people with diabetes in EU.

To address volume growth on account of increased penetration of its products in developed and emerging markets and also to support new biosimilar pipeline development and launches, Biocon Biologics is investing in expanding its manufacturing capacities in line with its approach of modular expansion. The company has also been undertaking strategic partnerships and acquisitions to rapidly expand its biosimilars portfolio and increase the addressable market opportunity.