

Press Release

## **Biocon's Biologics Drug Products Facility in Bengaluru Receives EIR from U.S. FDA**

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

*Bengaluru, Karnataka, India, November 05, 2019*

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced that it 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.

#### **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 that can expand access to a cutting-edge class of therapies to patients globally. It is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world and 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 EU, Australia, U.S. and Japan. Biocon Biologics has a product pipeline of 28 molecules, including 11 with Mylan, several with Sandoz and is developing many independently.

#### **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](http://www.biocon.com) & follow Biocon Limited on Twitter @bioconlimited

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### Forward Looking Statement: Biocon

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