

Press Release

Biocon Biologics Receives EU GMP Certification for Multiple Biosimilars Manufacturing Facilities in Bengaluru; Expands its Manufacturing Capacity

Includes Drug Substance and Drug Product Facilities for Pegfilgrastim, Trastuzumab, and Bevacizumab

Bengaluru, Karnataka, India: May 19, 2020:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today that its subsidiary Biocon Biologics India Ltd. has received the Certificate of GMP compliance from EMA for multiple Biologics Drug Substance (DS) and Drug Product (DP) manufacturing facilities at Biocon Park, Bengaluru.

These facilities are used for the manufacture of DS and DP for Biosimilars: Bevacizumab, Trastuzumab, Pegfilgrastim and secondary packaging of Insulin Glargine for EU markets, and were inspected in March 2020.

This approval expands Biocon Biologics' capacities multi-fold to address the growing needs of patients in the EU markets for Trastuzumab commercialized in March 2019 and for Pegfilgrastim expected to be commercialized soon. This certification would further enable the approval process of our biosimilar Bevacizumab, the Marketing Authorization Application for which is currently under review by the European authorities.

Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics India Ltd, said, *"We are extremely pleased with the EU GMP certification for our Biologics DP and DS manufacturing facilities in Bengaluru. This approval will support the penetration of Trastuzumab and Pegfilgrastim in Europe. This certification is expected to further enable the approval of biosimilar Bevacizumab in the EU. We remain committed to enhance access to our high quality biosimilars and global standards of quality and compliance and reaching the milestone of USD 1 billion in revenues in FY22. "*

Biocon Biologics has been making continued investments in building global scale, cost-competitive, complex manufacturing capabilities to address market opportunities worldwide. We expanded our production capacity for Pegfilgrastim Drug Substance through the new B-4 manufacturing facility in Bengaluru, which received U.S. FDA approval in November 2019 and started commercial operations subsequently. In 2019, we also expanded production capacity for our biosimilar Trastuzumab through a new



Drug Product (DP) filling line at the B-2 biologics facility, which received U.S. FDA approval in October 2019.

Biocon Biologics, through its partner Mylan, has commercialized two of its co-developed biosimilars, Trastuzumab and Insulin Glargine, in EU. The commercialization of biosimilar Pegfilgrastim in the EU is imminent. These approvals further strengthen our ability to bring products to patients in EU. Going forward, through our strong portfolio of in-market and in-review biosimilars we will pursue the path of growth in EU, where the market for biosimilars is sizable and growing.

Biocon Biologics 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 5 million patient lives and cross a revenue milestone of USD 1 billion in FY22 .

About Biocon Limited

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 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 US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. www.biocon.com Follow-us on Twitter: @bioconlimited

Biocon Biologics is a subsidiary of Biocon Ltd. 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’s portfolio of biosimilar molecules comprises a rich pipeline of approved and in-development biosimilars, which are an outcome of its high end R&D and global scale manufacturing expertise. The Company has commercialized three of its biosimilars in the developed markets like EU, U.S., Japan and Australia. It is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. Follow-us on Twitter: @BioconBiologics

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Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.