NOTIFICATION TO STOCK EXCHANGE

Company Statement

Biocon Biologics Receives EIR from U.S. FDA for Two Manufacturing Facilities, Inspection Stands Closed

Bengaluru, Karnataka, India – April 16, 2020

"This is to inform you that Biocon Biologics India Ltd., a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), has received the Establishment Inspection Report (EIR) from the U.S. FDA for the Pre-Approval Inspection (PAI) at two of its biologics manufacturing facilities in Bengaluru. The inspection was conducted between September 10 and September 19, 2019. Biocon Biologics has responded to the regulator on the eight observations from this inspection, in the month of October 2019.

Subsequent to the above inspection, Biocon Biologics has received approvals for the two products Trastuzumab (Drug Product) and Pegfilgrastim (Drug Substance) from the U.S. FDA in 2019. The receipt of the Establishment Inspection Report (EIR) indicates a successful closure of the inspection. This is an endorsement of our commitment to global standards of Quality and Compliance.

The formal closure of the U.S. FDA inspection is expected to enable filing of marketing authorization applications for our biosimilar products in several global markets. We stay committed to enable affordable access to our high quality biosimilars for millions of patients across the globe."

- Company Spokesperson

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