NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Bengaluru, Karnataka, India, July 27, 2024

US FDA Completes Inspection at Biocon Biologics' Facilities at Biocon Park, Bengaluru, India

"The U.S. Food and Drug Administration (FDA) conducted a combined cGMP inspection and Pre-Licensing Inspection (PLI) at Biocon Biologics' Facilities at Biocon Park, Bengaluru, India between July 15, and July 26, 2024.

The inspection scope included **six** (6) separate Biologics manufacturing units comprising **four** (4) Drug Substance and **two** (2) Drug Product manufacturing plants. In addition, the inspection also covered **five** (5) Analytical Quality Control Laboratories and **four** (4) Microbiology Laboratories, and **two** (2) Warehouses.

At the conclusion of the inspection, the FDA issued a Form-483 with observations that can be broadly categorized as: **one** (1) observation across the four Drug Substance facilities; **seven** (7) observations across the two Drug Product facilities; **two** (2) observations on the Analytical Quality Control Laboratories; **zero** (0) observations on the Microbiology Laboratories; and **zero** (0) observations on the Warehouse operations.

There were no observations related to Data Integrity or on Quality oversight at any of the facilities also, no repeat observations were noted by the agency during the inspection. Biocon Biologics will submit a comprehensive Corrective and Preventive Action (CAPA) plan to the agency and is confident of addressing these observations expeditiously.

We do not expect the outcome of these inspections to impact the supplies of our commercial products. Biocon Biologics remains committed to global standards of Quality & Compliance and to serving patients across the world."

– Company Spokesperson

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