NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Bengaluru, Karnataka, India, Oct 21, 2022

Biocon Biologics Insulins Facility in Malaysia Receives EU GMP Certification

"Biocon Biologics' integrated insulins manufacturing facility in Malaysia is approved by the European Medicines Agency following a site inspection in July 2022. The Company has received the Certificate of GMP Compliance from the representative European inspection authority, Health Products Regulatory Authority (HPRA), Ireland. This approval reflects the agency's determination that the manufacturing facilities for Drug Substances, Drug Products, Insulin Delivery Device Assembly, as well as Secondary Packaging and Warehousing areas are in compliance with the guidelines of Good Manufacturing Practices. This certificate enables the Company to continue addressing the needs of people with diabetes in the EU who require Insulin Glargine and Insulin Aspart.

"Biocon Biologics remains committed to the global standards of Quality and Compliance."

– Company Spokesperson

U.S. FDA Issues a CRL for the Biologics License Application for Insulin Aspart

"The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for Insulin Aspart filed by our partner Viatris (Mylan). The CRL did not identify any outstanding scientific issues with the product. The CRL references the Form 483 observations noted during the pre-approval inspection of Biocon Biologics' integrated insulins manufacturing facility at Malaysia in August 2022, which we disclosed on Aug 31, 2022.

"We have submitted a CAPA (Corrective and Preventive Action) plan to the U.S. FDA for review and remain confident in our ability to resolve these observations expeditiously.

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– Company Spokesperson

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