NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Biocon Biologics Receives Complete Response Letter from US FDA for Biosimilar Insulin Aspart

Bengaluru, Karnataka, India, October 7, 2023

"The U.S. Food and Drug Administration (US FDA) has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for Insulin Aspart. The CRL did not identify any outstanding scientific issues with the product. The CRL references the requirement for a satisfactory resolution of deficiencies from the pre-approval inspection (PAI) of our Malaysia facility for Insulin Aspart, held in August 2022.

The Company had submitted a comprehensive Corrective and Preventive Action (CAPA) plan in September 2022, that the agency found to be adequate and indicated that it would require a re-inspection of the Malaysia facility, prior to the approval of the application.

In February 2023, the Company submitted a report from an independent third-party consultant, providing evidence of CAPA completion and effectiveness. However, the PAI re-inspection was not scheduled prior to the goal date of October 6, 2023."

"The Company will continue to engage with the US FDA for an expeditious resolution and approval of its biosimilar Insulin Aspart application.

This decision has no impact on the manufacturing or distribution of the Company's existing commercial portfolio. Biocon Biologics is committed to bringing high-quality and affordable medicines to the United States." *– Company Spokesperson*

For more information: seema.ahuja@biocon.com