

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Bengaluru, Karnataka, India, February 29, 2024

“The U.S. Food and Drug Administration (FDA) conducted an inspection at Biocon Biologics Limited’s Biocon Campus (Site 1) facility between February 20-28, 2024.

This inspection pertains exclusively to the rh-Insulin (rhl) Drug Substance (DS) supply to a customer for veterinary use. The trigger for this inspection was a Pre-Approval Supplement (PAS) filed by our customer late last year.

At the conclusion of this inspection, the agency has issued Form 483s with 4 observations. The Company will submit a comprehensive Corrective and Preventive Action (CAPA) Plan to the U.S. FDA within the stipulated time and is committed to addressing these observations expeditiously.

The outcome of this inspection at Site 1 does not impact the manufacturing and distribution of the Company’s commercial products in the US market.

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

– Company Spokesperson

For more information: seema.ahuja@biocon.com