



## **NOTIFICATION TO STOCK EXCHANGE**

### **COMPANY STATEMENT**

#### **USFDA issues a CRL for the Biologics License Application for Insulin-R**

*Bengaluru, Karnataka, India, Jan 7, 2023*

“The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for the Insulin-R product filed by Biocon Biologics. The CRL cites additional data required in the BLA submission and an expectation of a satisfactory implementation of a CAPA plan pertaining to the Pre-Approval Inspection of our Bangalore facilities in Aug’22. We are in the process of comprehensively addressing the CRL.”

– Company Spokesperson, Biocon Biologics.