NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Bengaluru, Karnataka, India, Aug 31, 2022

"The U.S. Food and Drug Administration (US-FDA) conducted **three on-site inspections of Biocon Biologics' seven manufacturing facilities spanning two sites in Bengaluru, India and one at Johor, Malaysia.** These inspections started with the Bengaluru site on August 11, 2022 and concluded with the Malaysia site on August 30, 2022.

These inspections were triggered on account of three preapproval inspections for biosimilar Bevacizumab, rh-Insulin and Insulin Aspart and a capacity expansion inspection for biosimilar Trastuzumab. These included multiple drug substance and drug product facilities and other support infrastructure at these sites.

At the conclusion of these inspections, the agency has issued Form 483s with 11 observations each for the two sites in Bengaluru and 6 observations for the Malaysia site.

The observations primarily relate to the need for improving strategies for microbial control, enhancing quality oversight, augmenting the use of software applications & computerized tools to aid risk assessment & investigations and other procedural & facility upgrades.

We will submit Corrective and Preventive Action Plans (CAPA), to the US FDA in the stipulated time frame.

We do not expect the outcome of these inspections to impact the current supply of our products. Biocon Biologics remains committed to global standards of Quality and Compliance.

– Company Spokesperson

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