Notification to Stock Exchange

COMPANY STATEMENT

U.S. FDA Completes Pre-Approval Inspection of Two New Biocon Biologics Facilities in Bengaluru

Bengaluru, Karnataka, India, Sep 20, 2019

"The U.S. FDA conducted a Pre-Approval Inspection (PAI) at two of our new Biologics Manufacturing facilities in Bengaluru from Sep 10 to Sep 19, 2019. The inspection included a new Drug Substance (DS) and a Drug Product (DP) unit.

At the conclusion of the inspection we received a Form 483 with four observations for the new DS facility, three observations for the new DP facility and one general observation. We are confident of addressing these observations effectively through a Corrective and Preventive Action (CAPA) plan, expeditiously. The Pre-Approval Inspection of our new facilities does not have any impact on our current commercialization plans from our existing facilities." - *Company Spokesperson*

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