Notification to Stock Exchange

Biocon Company Statement

U.S. FDA Issues Complete Response Letter for New Drug Application for Insulin Glargine; Commercialization Plans Remain Unchanged

Bengaluru, Karnataka, India, Aug 31, 2019

"The U.S. FDA has issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for Insulin Glargine filed by our partner Mylan. The CRL has been issued pending completion of the Corrective And Preventive Actions (CAPAs) submitted to the U.S. FDA in response to the observations made at the conclusion of the pre-approval inspection of our insulin manufacturing facility in Malaysia in June 2019.

The CRL did not identify any outstanding scientific issues with the application. We remain confident of the quality of our application and do not anticipate any impact of this CRL on the commercial launch timing of our Insulin Glargine in the U.S.

We remain committed to global standards of Quality & Compliance and are working closely with our Partner and the regulator to complete these CAPAs to the satisfaction of the U.S. FDA."

- *Company Spokesperson*

U.S. FDA completes surveillance (routine) cGMP inspection of one of our Biologics Drug Product facilities in Bengaluru

"The U.S. FDA conducted a cGMP inspection at one of our Biologics Drug Product facilities in Bengaluru from Aug 22 to Aug 30, 2019. The inspection concluded with four observations which we believe will not impact supplies from this facility. We are confident of addressing these observations through a Corrective and Preventive Action plan in a timely manner."

- *Company Spokesperson*

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