

NOTIFICATION TO STOCK EXCHANGE

Company Statement

Biocon's Insulin Manufacturing Facility in Malaysia Receives EIR from U.S. FDA with Voluntary Action Indicated (VAI) Classification, Inspection Stands Closed

Bengaluru, Karnataka, India, April 1, 2020

"This is to inform you that Biocon Sdn Bhd., a subsidiary of Biocon Limited (BSE code: 532523, NSE: BIOCON) has received the Establishment Inspection Report (EIR) from the U.S. FDA for the Pre-Approval Inspection (PAI) of its Insulins manufacturing facility in Malaysia, for Insulin Glargine. The inspection was conducted between Feb 10 and Feb 21, 2020.

The Inspection has been closed with a "VAI" (Voluntary Action Indicated) classification in the EIR, for the three observations issued at the conclusion of the inspection in Feb 2020. This is an endorsement of our commitment to global standards of Quality and Compliance.

The closing of the USFDA Inspection of our Malaysia Facility is an important milestone in our journey of developing Insulin Glargine for patients in the US. Our Insulin Glargine (Semglee®) application filed by our partner Mylan, with the USFDA under the 505(b)(2) NDA pathway, is currently under review."

- Company Spokesperson

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