Biocon Company Statement on ANSM Inspection Report

Biocon Receives GMP approval for Biologics Drug Substance facilities from French Regulator; Drug Product facility to be re-inspected

Bengaluru, Karnataka, India, July 9, 2017:

"The French inspecting authority (ANSM) conducted pre-approval inspection audits of our Bangalore drug substance and drug product sites related to the pending EMA Marketing Authorization Applications for Trastuzumab, Pegfilgrastim, and related to Insulin Glargine (pen assembly only).

While there were no critical observations mentioned in the final report, ANSM notified Biocon that the receipt of a GMP compliance certificate for the drug product facility will require a follow up inspection from ANSM to verify implementation of the proposed corrective and preventive actions (CAPAs). ANSM has reviewed the proposed CAPA plan and Biocon is progressing towards completion of the implementation of these CAPAs. Biocon, with its partner Mylan, will work with the French and European regulatory authorities with regard to the follow-up inspection of the drug product facility and the Marketing Authorization Applications with the goal of an early re-inspection.

We are pleased however that ANSM has issued GMP compliance certificates for our two drug substance manufacturing facilities in Bangalore. This is important as the drug substance manufacture is core to the production of the actual biologic product in GMP compliance.
Biocon is committed to ensuring the highest level of quality in all of its products."

- Company Spokesperson

For further information or query, please reach out to:

Seema Ahuja	**Rumman Ahmed**
VP & Global Head of Communications	Sr. Manager-Corporate Communications
Biocon Limited	Biocon Limited
T: +91-80-2808-2222, M:+91-9972317792	T: +91 80 28082223, M:+91-9845104173
Email: seema.ahuja@biocon.com	Email: rumman.ahmed@biocon.com
Investor Relations	
Saurabh Paliwal Head, Investor Relations	T: +91 80 6775 2040, M: +91 95383 80801 saurabh.paliwal@biocon.com