Company Statement on Resubmission of Biosimilar Trastuzumab and Pegfilgrastim Dossiers with EMA

Bengaluru, Karnataka, India, November 7, 2017:

Biocon´s partner Mylan has resubmitted the Marketing Authorization Applications (MAAs) for our proposed biosimilar trastuzumab and pegfilgrastim with the European Medicines Agency (EMA) as per the administrative protocol. This follows the earlier withdrawal of both applications in response to the audit of our aseptic drug product facility by the designated European authority. Biocon has completed the Corrective and Preventive Actions (CAPAs), including the facility modifications, in response to the audit observations and expects these to be verified during re-inspection.

- Company Spokesperson