

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Biocon Biologics and Viartis Receive European Commission Approval for Kixelle, Biosimilar Insulin Aspart

Bengaluru, India; February 12, 2021:

“This is to inform that **Biocon Biologics Ltd.**, a subsidiary of **Biocon Ltd. (BSE code: 532523, NSE: BIOCON)**, has announced that **Kixelle**, a biosimilar Insulin Aspart co-developed with Viartis Inc. (NASDAQ: VTRS), has received marketing authorization approval from the European Commission following the positive recommendation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency. **Kixelle**, a fast-acting insulin analog indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above, has been approved as a 100 units/ml solution for injection in vial and pre-filled pen presentations.

The centralized marketing authorization granted by the EC is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

“The European Commission’s approval of our biosimilar Insulin Aspart is an endorsement of the quality of our product and the data generated during its development. The approval will enable affordable access to a rapid acting insulin analog for people with diabetes in the EU, where our biosimilar Insulin Glargine, a long acting insulin analog, is already addressing patients’ needs for an affordable quality treatment option. We are leveraging our science, expertise and global scale manufacturing to expand access to our high quality, affordable biologics, globally.”

-- Company Spokesperson, Biocon Biologics.

For more information

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