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Biocon, Mylan receive FDA approval of Insulin Glargine

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FDA approval marks a significant milestone to help increase access and affordability of insulin for the millions of Americans living with diabetes

Biocon Ltd. and Mylan N.V. have announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Semglee™ (insulin glargine injection), in vial and pre-filled pen presentations, to control high blood sugar in adults with type 2 diabetes and adult and pediatric patients with type 1 diabetes. Semglee has an identical amino acid sequence to Sanofi's Lantus® and is approved for the same indications.

Semglee, co-developed by Mylan and Biocon Biologics, was approved as a drug product under the 505(b)(2) NDA pathway and is now deemed a biologic under section 351(a) in accordance with the Biologics Price Competition and Innovation Act in line with other insulin products.

Kiran Mazumdar Shaw, Chairperson, Biocon, said: "The approval of our insulin glargine by the U.S. FDA marks the culmination of a long journey. As an organisation committed to making insulin-based therapy increasingly accessible for people with diabetes globally, I am glad this approval will enable us to serve the needs of patients in the U.S. The approval is also an endorsement of our science, scale and expertise to develop high quality, more affordable insulins and shift the access paradigm in favour of patients, taking us closer to realizing our aspiration of reaching 'one in five' insulin dependent people with diabetes worldwide."

The approval for Semglee was based on a comprehensive analytical, preclinical and clinical program (including the INSTRIDE studies) which confirmed the PK/PD, efficacy, safety and immunogenicity of Semglee in comparison to Lantus in patients with type 1 and type 2 diabetes.