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Biocon Biologics expands diabetes portfolio with US FDA approval of Kirsty

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First and only interchangeable rapid-acting Insulin Aspart in the United States

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of India-based Biocon Ltd. has announced that the US Food and Drug Administration (FDA) has approved Kirsty™ (Insulin Aspart-xjhz), 100 units/mL as the first and only interchangeable biosimilar to NovoLog® (Insulin Aspart).

KIRSTY is a rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. KIRSTY will be available as a single-patient-use prefilled pen for subcutaneous use and a multiple-dose vial for subcutaneous and intravenous use.

The FDA approval of KIRSTY expands Biocon Biologics' biosimilar insulin portfolio, which also includes the first approved interchangeable biosimilar, Semglee® (Insulin Glargine-yfgn Injection). KIRSTY has been available in Europe and Canada since 2022.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd., said, "The FDA approval of Kirsty™, the first and only interchangeable biosimilar rapid-acting Insulin Aspart in the US, is a significant step forward in our efforts to make insulin more accessible and affordable. It builds on the foundation we laid with Semglee®, reinforcing our commitment to scientific excellence and patient-centric innovation. With Kirsty™, we are expanding treatment choices for people living with diabetes and advancing our ambition to be a global leader in addressing unmet needs in diabetes care."