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Biocon Biologics and Civica expand partnership to launch private-label insulin glargine in US

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Additional treatment options for the 38.4 million US patients living with diabetes



Bengaluru-based Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd., has announced expansion of its strategic collaboration with Civica, Inc. to include a new Insulin Glargine medicine that will benefit patients in the United States by increasing supply of high-quality affordable insulins.

The multi-year transformational agreement between Biocon Biologics and Civica creates an exclusive distributorship arrangement where Biocon Biologics will manufacture and supply Insulin Glargine medicine to Civica, and Civica will commercialize under Biocon Biologics' existing marketing approval (a private label agreement).

Civica will distribute, promote, and sell the medicine in the United States under a separate Civica label and trade dress, and in California, the product will carry the CalRx brand. Biocon Biologics will continue to directly commercialise Biocon Biologics' own Insulin Glargine-yfgn medicine, which was approved by the US Food and Drug Administration (FDA) in July 2021 as the first interchangeable biosimilar.

No technology transfer is involved in the agreement and Biocon Biologics will continue to own the intellectual property and marketing authorization associated with Insulin Glargine. Additional terms of the agreement are not disclosed.

This agreement expands the relationship between the two organisations that previously announced that Biocon Biologics will provide Civica with Insulin Aspart drug substance to manufacture in the United States.

Insulin glargine-yfgn injection is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of use: Insulin glargine-yfgn is not recommended for the treatment of diabetic ketoacidosis.