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Sanofi announced that the US Food and Drug Administration (FDA) has approved Adlyxin (lixisenatide), a once-daily mealtime GLP-1 receptor agonist injection indicated as an adjunct to diet and exercise for the treatment of adults with type 2 diabetes.

"The approval of Adlyxin reaffirms our continued commitment to addressing the challenges faced by people living with diabetes when trying to reach and maintain their individual blood glucose (HbA1c) targets," said Mr Peter Guenter, EVP, Head, Global Diabetes & Cardiovascular Business Unit, Sanofi. "We are pleased with this approval, as it offers us the opportunity to continue helping patients treated with basal insulin who remain uncontrolled."

Also Read: FDA grants EUA to Siemens' Zika assay

The approval of Adlyxin was based on FDA review of results from the GetGoal clinical program and findings from the ELIXA trial, which successfully addressed the FDA's request to demonstrate CV safety.

The GetGoal clinical program, which included 13 clinical trials involving more than 5,000 adults with type 2 diabetes worldwide, evaluated the safety and efficacy of lixisenatide in adults with type 2 diabetes.

All studies of the GetGoal program successfully met the primary efficacy endpoint of HbA1c reduction.

The most common adverse events reported for Adlyxin included nausea, hypoglycemia and vomiting.

Adlyxin will be available in a disposable pre-filled pen in a single dose of 20 micrograms.

Patients will also receive a disposable pre-filled pen in a single dose of 10 micrograms that they should initiate once daily for 14 days.

On Day 15, patients will increase dosage to 20 micrograms once daily.

Adlyxin is approved under the proprietary name, Lyxumia in more than 60 countries and marketed in over 40.

Commercial launches include most EU countries, Japan, Brazil, Mexico and India. Adlyxin was in-licensed from Zealand Pharma.