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Japan approves Lyxumia for diabetes therapy

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Singapore: Drug major, Sanofi has received approval of Japan's Ministry of Health, Labour and Welfare (MHLW) for manufacturing and distribution of Lyxumia (lixisenatide) for the treatment of type 2 diabetes.

Lyxumia, the first once-daily prandial GLP-1 receptor agonist (RA), is also the first GLP-1 RA approved in Japan for use in combination with basal insulin. Lyxumia is indicated for patients with type 2 diabetes mellitus when the following do not provide adequate glycemic control: diet and exercise and sulfonylureas (with and without biguanides) or diet and exercise and soluble prolonged-acting or intermediate-acting insulin (with and without sulfonylureas).

"Lyxumia, as the first GLP-1 receptor agonist approved in Japan for use in combination with basal insulin, will be a valuable new treatment option for many of the country's 6 million plus people living with type 2 diabetes," said Mr Pierre Chancel, senior VP, global diabetes, Sanofi. "The MHLW decision immediately enables the use of Lyxumia, which works in a way that complements basal insulin."

Although basal insulin treatment provides effective control of overall glucose excursions by primarily targeting fasting plasma glucose (FPG), as diabetes progresses over time, patients treated with basal insulin may no longer stay at their HbA1c goals, despite good control of FPG. When this happens, adding a medicine such as Lyxumia, which targets post-prandial glucose, may be an effective strategy to further lower blood glucose levels and reach HbA1c goals.

MHLW approval in Japan is supported by the international GetGoal program, which included a total of 11 clinical trials involving more than 5,000 patients with type 2 diabetes. Among these trials is the pivotal Phase III study GetGoal-L-Asia, which included 159 patients from Japan.

Lyxumia is approved in Mexico, the European Union, Australia and Japan. The New Drug Application for lixisenatide in the United States is currently being reviewed.

Lyxumia (lixisenatide) is a glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of patients with type 2 diabetes mellitus. GLP-1 is a naturally-occurring peptide hormone that is released within minutes after eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate glucose-dependent insulin secretion by

pancreatic beta cells.