# Lyxumia® is first diabetes therapy of its class approved in Japan for use in combination with basal insulin

***- First once-daily prandial GLP-1 receptor agonist offering a new treatment option for Japanese people living with type 2 diabetes -***

**Paris, France** - **June 28, 2013** - Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved the 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 Pierre Chancel, Senior Vice-President, Global Diabetes at 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),[1,2] as diabetes progresses over time, patients treated with basal insulin may no longer stay at their $HbA_{1c}$ 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 $HbA_{1c}$ 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.[3]

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

## About Lyxumia® (lixisenatide)

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.

Lyxumia was in-licensed from Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), www.zealandpharma.com, and is approved in Europe for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate

glycemic control. Lyxumia is also approved in Mexico and Australia for the treatment of adults with type 2 diabetes. Lyxumia is the proprietary name approved by the European Medicines Agency and other health authorities for the GLP-1 RA lixisenatide. The proprietary name for lixisenatide in the United States is under consideration.

### About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services and devices, including innovative blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes.

### About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### References


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2. Riddle et al. Contributions of basal and postprandial hyperglycemia over a wide range of A1c levels before and after treatment intensification in type 2 diabetes. *Diabetes Care* 2011; 34(12): 2508–2514.
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