Company Announcement
No. 17/2013

Zealand informs that Lyxumia® (lixisenatide), invented by Zealand and licensed to and marketed by Sanofi, has been approved in Japan for the treatment of Type 2 diabetes

— Zealand's world-leading peptide innovation provides for the approval of Lyxumia® as the first GLP-1 agonist in Japan to be used in combination with basal insulin

— Lyxumia® is also approved in the European Union, Australia and Mexico, in which markets Sanofi is in the process of making the product available for patients and their caregivers

— Under the license agreement with Sanofi, Zealand is entitled to tiered low double-digit percentage royalties on world-wide sales of Lyxumia®

Copenhagen, 28 June 2013 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") informs that today Lyxumia® was approved by Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of Type 2 diabetes. Lyxumia® (lixisentatide) is a once-daily prandial GLP-1 receptor agonist invented by Zealand and with world-wide rights to develop and market the product licensed to Sanofi (EURONEXT: SAN and NYSE: SNY) for the treatment of Type 2 diabetes.

Lyxumia® is the first of Zealand's peptide drug innovations to have reached the market for the benefit of patients.

Commenting on the Japanese approval of Lyxumia® and the importance of this milestone to Zealand, President and CEO, David Solomon said:

"We are delighted that our drug invention, lixisenatide (developed and marketed as Lyxumia® by Sanofi) has now reached the market also in Japan to the benefit of the large number of patients with Type 2 diabetes, whose blood glucose is not adequately controlled with existing medication, including patients on basal insulin.

"Zealand is world leading in peptide drug innovation and design, and the regulatory approvals of Lyxumia® now in Europe, Japan, Australia and Mexico and the encouraging launch by Sanofi, a top-leading diabetes company, of the product in the first European markets, is a strong validation of our capabilities. Importantly also, the revenue to Zealand

from Sanofi's sales of Lyxumia® is expected to help leverage our pipeline activities and further increase our corporate value."

In Japan, Lyxumia® is the first GLP-1 agonist based therapy to be approved for use in combination with basal insulin., 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).

In a Sanofi press release today, Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi, commented:

"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," and he continued

"The MHLW decision immediately enables the use of Lyxumia, which works in a way that complements basal insulin."

Effective control of overall glucose excursions associated with diabetes requires good control of both fasting plasma glucose (FPG) and post-prandial glucose (PPG) levels. Treatment with basal insulin provides effective control of HbA1c by primarily targeting FPG [1,2]. As diabetes progresses over time, however, 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 (PPG), may be an effective therapeutic strategy for these patients to improve overall glucose levels and reach HbA1c goals.

Lyxumia® is now approved in the European Union, Japan, Australia and Mexico. In the United States, the New Drug Application (NDA) submitted for the product to the Food and Drug Administration (FDA) by Sanofi is currently being reviewed.

Financial outlook for 2013 and terms of the agreement with Sanofi

The approval of Lyxumia® in Japan does not change the 2013 Financial Outlook for Zealand as announced by the company in its Interim Report for Q1 2013 on 15 May 2013 (Company Announcement no. 14/2013).

Under the license agreement with Sanofi, Zealand is entitled to up to a total of USD 275 million in milestone payments, of which up to potentially USD 175 million are outstanding. Further, Zealand will receive tiered low double-digit percentage royalties on Sanofi's global sales of Lyxumia® and fixed low double-digit percentage royalties on global full net sales of the Lantus®/Lyxumia® combination product.

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References

1. Aronoff et al. Glucose metabolism and regulation: Beyond insulin and glucagon. *Diabetes Spectrum* 2004; 17(3): 183–190.
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.

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.

Lixisenatide is invented by Zealand and world-wide rights to develop and market the product are licensed to Sanofi (EURONEXT: SAN and NYSE: SNY). Lixisenatide is approved and marketed by Sanofi in Europe under the brand name Lyxumia®, 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. The proprietary name for lixisenatide in the United States is under consideration.

About Zealand

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") is a biotechnology company based in Copenhagen, Denmark. Zealand specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company's focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its lead drug invention is lixisenatide, a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide is approved in Europe, Japan, Australia and Mexico and marketed by Sanofi under the name of Lyxumia®.Lixisenatide is under regulatory review in a large number of other countries globally, including in the US (NDA submission accepted in Feb 2013).

Zealand has a partnering strategy for the development and commercialization of its products and in addition to the collaboration with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury.

For further information: www.zealandpharma.com.
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