Company Announcement
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Zealand Pharma announces once-daily Lyxumia® (lixisenatide) approved in Europe for the treatment of Type 2 Diabetes

– *Under the agreement with Sanofi, the company is entitled to tiered low double-digit percentage royalties on global sales of Lyxumia®*

Copenhagen, 4 February 2013 - Zealand Pharma (NASDAQ OMX Copenhagen: ZEAL) announces that its partner Sanofi (EURONEXT: SAN and NYSE: SNY) has been granted a Marketing Authorization in Europe for Lyxumia® (lixisenatide) by the European Commission.

Lyxumia®, the once-daily prandial GLP-1 receptor agonist, was invented by Zealand Pharma and licensed to Sanofi, which holds global commercial rights for the drug. Lyxumia® has been indicated for the treatment of Type 2 diabetes in adults 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.

The European Commission's decision to grant Marketing Authorization in Europe for Lyxumia® is based on results from Sanofi's international GetGoal Phase III program, involving more than 5,000 patients with Type 2 diabetes in 11 clinical studies. As part of the program, a large number of patients were studied for an evaluation of the effects of Lyxumia® in combination with basal insulin (706 patients treated with Lyxumia® in three trials) [1].

Results from GetGoal have enabled Lyxumia® to become the first once-daily GLP-1 receptor agonist with a predominantly prandial glucose lowering effect to be indicated for use on top of basal insulin and in combination with oral anti-diabetic medications. The results showed that treatment with Lyxumia® gave significant HbA1c reductions, a pronounced lowering of post-prandial glucose (after meal blood sugar levels) and a beneficial effect on body weight in adult patients with Type 2 diabetes. GetGoal results also showed that Lyxumia® had a favorable safety and tolerability profile in most patients, with mild and transient nausea and vomiting, the most common adverse events observed in the GLP-1 receptor agonist class, and a limited risk of hypoglycemia.

Commenting on this announcement**, David Solomon, President and CEO of Zealand Pharma, said:**
"The European approval of Lyxumia® is a key milestone for Zealand Pharma. The achievement of commercial status is the ultimate endorsement of Lyxumia's therapeutic potential and a validation of Zealand Pharma's peptide drug discovery and development capabilities. We are extremely gratified that our first discovered product, lixisenatide – branded as Lyxumia® by Sanofi, will soon be available for diabetes patients throughout Europe."

"In clinical practice today, there is a strong need for more differentiated diabetes treatments. Patients with Type 2 diabetes are not all alike and the availability of additional GLP-1-based drugs with new pharmacological profiles is important to ensure a more effective management of diabetes," said ***Dr Filip K. Knop, MD, PhD, of Gentofte Hospital, University of Copenhagen.*** *"One issue is that patients treated with basal insulin often move away from their target HbA1c despite well-controlled fasting plasma glucose.*

Adding a short acting GLP-1 receptor agonist with a pronounced effect on post-prandial glucose like once-daily Lyxumia® may be a good way of getting these patients back at target without increasing the risk of hypoglycemia."

"With the European approval of Lyxumia®, we now have a simple new tool to help patients with Type 2 diabetes further reduce HbA1c, with the benefit of weight loss and limited risk of hypoglycaemia. This well-tolerated therapy is of specific interest to patients who are on oral treatments and / or basal insulin and do not manage to maintain their HbA1c targets," said **Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi** in a press release from Sanofi today. *"With a single daily injection and only one step to maintenance dose, Lyxumia® is a positive addition to the Sanofi portfolio, and represents another step forward in our efforts to advance scientific excellence and develop new therapeutic solutions that improve outcomes for people with diabetes, an area of significant unmet medical need."*

Marketing Authorization for Lyxumia® in Europe is applicable to the 27 Member States of the European Union, as well as Iceland, Lichtenstein and Norway, and follows the positive recommendation issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency on 15 November 2012.

Applications for regulatory approval of Lyxumia® in Type 2 diabetes have also been submitted in several other countries around the world and are currently under review. In the US, a decision on NDA filing acceptance is expected from the FDA in Q1 2013.

Financial guidance for 2013 and the terms of the Sanofi agreement

As earlier announced, there is no milestone payment to Zealand Pharma associated with the approval of Lyxumia® in Europe. The company will provide financial guidance for 2013 in connection with the release of its 2012 full-year announcement on 14 March 2013.

Under the license agreement with Sanofi, which covers lixisenatide and combination products, including lixisenatide, Zealand Pharma is eligible to receive remaining development, regulatory and sales milestone payments of up to USD 215 million, which include USD 40 million for a depot formulation of Lyxumia® not currently in active development [2].

Further, the company is entitled to tiered low double-digit percentage royalties on global net sales of Lyxumia® and fixed low double-digit percentage royalties on full net sales of combination products, including lixisenatide [2].

References

1. http://clinicaltrials.gov/ct2/results?term=GetGoal. Date accessed: December 2012.
2. Zealand Pharma pays 13% to Alkermes (former Elan) and 0.5% to SIP® technology inventor on all income from lixisenatide.

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About lixisenatide (Lyxumia®)

Lixisenatide (Lyxumia®) 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 stimulate glucose-dependent insulin secretion by pancreatic beta cells and suppress glucagon secretion from pancreatic alpha cells..

Lixisenatide is invented by Zealand Pharma and global rights to the product are licensed to Sanofi. Lyxumia® is the proprietary name approved by the European Medicines Agency (EMA) for the GLP-1 RA lixisenatide.

About Zealand Pharma

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand Pharma 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 diabetes/metabolic diseases, and its lead drug invention is lixisenatide (Lyxumia®), a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lyxumia® is approved in Europe (February 2013), and under regulatory review in a large number of other countries globally. In the US, a decision on NDA filing acceptance is expected from the FDA in Q1 2013.

Zealand Pharma 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. Zealand Pharma focuses its activities in disease areas where existing treatments fail to adequately serve patient needs and where the market potential for improved treatments through the use of peptide drugs is high. For further information: www.zealandpharma.com

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, a global and diversified 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).