

Zealand informs that data presented on Lyxumia[®] support known complementary effects of this diabetes medicine in combination with basal insulin

- A sub-analysis of results from the GetGoal-L study shows that Lyxumia[®] added to basal insulin lowered blood sugar (HbA1c) especially when fasting glucose was controlled

- The data were presented today at the 49th Annual Meeting of EASD

Copenhagen, 24 September, 2013 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) (“Zealand”) informs that new sub-analysis results from the GetGoal-L Phase III clinical study show that reductions in HbA1c with Lyxumia[®] (lixisenatide), when added to basal insulin, were greatest in patients with type 2 diabetes who had well-controlled baseline fasting plasma glucose (FPG). Reductions in body weight with Lyxumia[®], when added to basal insulin, were also greatest in this group. The new results were presented today in an oral session at the 49th Annual Meeting of the European Association for the Study of Diabetes in Barcelona.

Lixisenatide, a once-daily prandial GLP-1 receptor agonist for the treatment of type 2 diabetes, was invented by Zealand, and is marketed in Europe and Japan by Sanofi (EURONEXT: SAN and NYSE: SNY), who holds global development and commercial rights to the product.

As noted by Sanofi in a press release today, Type 2 diabetes is a progressive disease and patients treated with basal insulin may over time no longer maintain their target HbA1c level (2 to 3 months average blood sugar levels) despite typically sustaining good control of FPG with basal insulin.

For these patients, Lyxumia[®] can through its predominant effect on post-prandial glucose (PPG, after meal blood sugar) significantly reduce HbA1c in complementary action with basal insulin. A treatment regimen that targets PPG as well as FPG could be an effective way to improve disease management in patients with type 2 diabetes who are not at their target HbA1c despite controlled FPG.



Commenting on the presented results, Zealand's Chief Executive Officer, David Solomon, said:

"We are delighted to see these further positive data on Lyxumia[®], the first peptide medicine invented by Zealand. The data presented today at EASD complement previous findings on the beneficial effects of Lyxumia[®] in particular in combination with basal insulin. We see Lyxumia[®] as an important new diabetes medicine with a unique therapeutic profile. Marketed by Sanofi who has a strong global presence and a deep understanding of patient needs in this field, we firmly believe our invention will grow to an important product providing a sustainable revenue stream for our company going forward." And he added: "To explore the full potential for Lyxumia[®] in combination with basal insulin, Sanofi is planning to start Phase III development of a single Fixed-ratio Lyxumia[®]/Lantus[®] combination product in the first half of 2014. We are convinced that such product holds promise also as a very valuable treatment option for diabetes patients."

Results of the GetGoal sub-analysis

This sub-analysis examined 496 patients with type 2 diabetes and inadequate glucose control. Results showed that the addition of lixisenatide to basal insulin treatment, with or without metformin (oral anti-diabetic therapy), reduced overall HbA1c, body weight and post-breakfast self-monitored post-prandial glucose in all groups. These effects were greater in patients with relatively well-controlled baseline FPG levels (below or equal to 6.7 mmol/L; FPG in people without diabetes is ~5.5 mmol/L¹) compared to those with higher baseline FPG levels (between 6.7 and 8.9 mmol/L, and over 8.9 mmol/L, respectively).

The GetGoal-L sub-analysis abstract is entitled: *'Therapeutic efficacy of lixisenatide added to basal insulin is greater when FPG is well-controlled'* (Vidal J, et al. (Abstract no. OP 6)).

Reference

1. International Diabetes Federation. Global Guideline for Type 2 Diabetes (2012). Available at: www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf. Date accessed: September 2013.

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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 was invented by Zealand with global development and commercialization rights licensed to Sanofi (EURONEXT: SAN og NYSE: SNY) Lyxumia® 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, Australia, Japan and Brazil for the treatment of adults with type 2 diabetes. Sanofi plans to resubmit the New Drug Application for lixisenatide in the United States in 2015, after completion of the ELIXA cardiovascular outcomes study. Lyxumia is the proprietary name approved by the European Medicines Agency and other health authorities for the GLP-1 RA lixisenatide.

The Lyxumia® pen is the winner of a number of innovative design awards, including the Red Dot Award, the Good Design Award, and the iF Product Design Award.

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 prandial GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide (marketed by Sanofi as Lyxumia®) is approved in Europe and Japan and under regulatory review in a number of other countries globally. In the U.S., an NDA is planned to be submitted in 2015, after completion of the ELIXA CV outcome study.

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

For further information: www.zealandpharma.com.

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