Company Announcement
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Zealand informs that new data presented at the World Diabetes Congress support flexibility in timing of administration for Lyxumia®

- ***Once-daily Lyxumia® exerts similar glucose lowering effect whether administered before breakfast or before the main meal; Primary study endpoint met.***
- ***Lyxumia®, invented by Zealand for the treatment of Type 2 diabetes and licensed globally to Sanofi, was first launched in March 2013 and is being rolled-out in Europe and RoW, where approved.***
- ***Sanofi remains on schedule to start Phase III studies with the combination of Lyxumia® and Lantus®, the investigational Lixilan fixed-ratio product, in the first half of 2014.***

Copenhagen, 5 December 2013 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") informs that Sanofi (EURONEXT: SAN and NYSE: SNY) today provided results of a 24-week Phase IIIb clinical study showing that Lyxumia® (lixisenatide) met the primary endpoint of non-inferiority in blood sugar lowering (HbA1c) when administered either before breakfast or before the main meal of the day. These results support that lixisenatide can effectively lower blood sugar at either time of administration.

The results also showed that a mean change in body weight of -2.6 to -2.8kg, was achieved regardless of the meal before which lixisenatide was administered. In addition, gastro-intestinal tolerability was comparable regardless of time of administration, with no cases of severe hypoglycemia. The data were presented in an oral session at the International Diabetes Federation's (IDF) World Diabetes Congress 2013, Melbourne, Australia[1)].

Commenting on the new data, Zealand's Chief Executive Officer, David Solomon, said: *"These additional results corroborate the usefulness and attractiveness of Lyxumia® as a once-daily prandial injectable diabetes therapy with flexibility for patients in terms of timing of administration. We are excited about the prospects for Lyxumia® as a significant diabetes medication and in particular about its attributes in combination with basal insulin. The next important milestone in the full exploration of the therapeutic potential of this product will be the scheduled commencement of Phase III studies with the Lyxumia® and Lantus® combination product, Lixilan, in H1 2014."*

Results of Analysis
The 24-week Phase IIIb study examined 451 patients with Type 2 diabetes, uncontrolled on metformin alone and randomized to lixisenatide either prior to prior to breakfast or the main meal. Lunch (as defined by questioning patients) was the main meal of the day for 53% of patients.

The primary endpoint of the study was to demonstrate non-inferiority in HbA1c decrease at 24 weeks from baseline, when lixisenatide was injected prior to the main meal of the day vs. breakfast. The endpoint was successfully achieved with mean HbA1c reductions of 0.65% and 0.74% respectively. In addition, 43.6% of patients in the main meal group and 42.8% in the breakfast group achieved HbA1c below 7% at week 24. The mean change in body weight was -2.6kg in the main meal group and -2.8kg in the breakfast group. Gastrointestinal tolerability was comparable between the two groups (nausea 14.7% and 15.5% and vomiting 2.7% and 3.5%, respectively) and the incidence of symptomatic hypoglycemia was low in both groups, with no severe cases.

1) The study abstract is entitled: '*Flexibility in timing of lixisenatide administration prior to either the main meal of the day or the breakfast in T2DM patients*' (Ahren B, et al.) World Diabetes Congress, oral presentation, December 5, 2013, 10:45−12:45 [ABS OP-0454].

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About Lyxumia® (lixisenatide)
Lyxumia® (Lixisenatide) is a glucagon-like peptide-1 receptor agonist (GLP-1 RA) invented by Zealand 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.

Global rights to develop and commercialize the product are licensed to Sanofi. 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. Lixisenatide is also approved in Mexico, Australia, Japan, Brazil, Columbia and Chile 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 Good Design Award 2012 and the iF Product Design Award. The variant of the Lyxumia pen used in Japan won the Good Design Award (G Mark) 2013.

About Zealand Pharma

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 invented product is lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, which is licensed globally to Sanofi. Lixisenatide (marketed by Sanofi as Lyxumia®) is approved in several countries, including 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 Cardiovascular 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.

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