

Press Release
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Zealand provides summary of new clinical data and information on Lyxumia[®] (lixisenatide) and LixiLan presented at the American Diabetes Association's (ADA) 74th Scientific Sessions

- ***Lyxumia[®] (lixisenatide): Results from an 8-week head-to-head study versus liraglutide support lixisenatide's differentiated profile as the first once-daily GLP-1 agonist with a pronounced lowering effect on meal-related blood sugar***
- ***LixiLan: Results from a Phase IIb study of the fixed-dose combination of Lyxumia[®] with Lantus[®] show robust blood sugar reduction (HbA1c to 6.3%) with weight loss, no increased hypoglycemia versus Lantus[®] and a very low incidence of nausea (7.5%) and vomiting (2.5%)***
- ***In an IR Conference call, Sanofi informed that resubmission of a US NDA for lixisenatide is expected in Summer 2015 and confirmed planned NDA submission for LixiLan as early as the end of 2015***

Copenhagen, 17 June 2014 – Zealand Pharma A/S ("Zealand") (NASDAQ OMX Copenhagen: ZEAL) provides a summary of new clinical data and information presented on Lyxumia[®] (lixisenatide) and on LixiLan, the fixed-ratio combination of Lyxumia[®] with Lantus[®], during the American Diabetes Association's 74th Scientific Sessions, held in San Francisco, 13 – 17 June 2014.

Lixisenatide is Zealand's own-invented once-daily prandial GLP-1 agonist, developed and marketed globally by Sanofi (EURONEXT: SANF.CO).

Commenting on the new data and the prospects for Lyxumia[®] and LixiLan, **David Solomon, President and Chief Executive of Zealand, said:**

"The new data presented at ADA provide further positive evidence of the differentiated therapeutic profile of Lyxumia[®] which makes this medicine particularly well-suited for combination treatment with basal insulin. In this respect, we are also pleased to note the Phase IIb results on LixiLan, showing that the fixed-ratio combination of Lyxumia[®] and Lantus provides a solid reduction in blood glucose with weight loss, very low GI events and no increased hypos versus Lantus[®] alone. We look forward to following Sanofi's continued progress towards regulatory filing for lixisenatide and LixiLan in the US."



In an 8-week pharmaco-dynamic study head-to-head versus liraglutide, lixisenatide showed a significantly more pronounced lowering effect on post-prandial (after-meal) blood glucose (blood sugar) when both are added to optimally titrated Lantus[®] (insulin glargine).

In the study, lowering of post-prandial glucose was measured as change from baseline in incremental area under the glucose curve for 4 hours after a standardized solid breakfast, at week 8. Findings also showed that while both lixisenatide and liraglutide lowered blood glucose (HbA_{1c}) when added to optimally titrated insulin glargine, lixisenatide treatment also resulted in significantly delayed gastric emptying vs liraglutide, fewer reports of gastrointestinal adverse events, a lower mean increase in heart rate and smaller increases from baseline to week 8 in pancreatic enzyme (amylase and lipase) levels. The most commonly reported adverse events in the study were symptomatic hypoglycemia and nausea.

Lyxumia[®] is approved in 40 countries, including Europe and Japan. Launched in the first countries in April 2013, the product is being rolled-out country by country by Sanofi. In the US, Sanofi plans for an NDA resubmission in summer 2015.

Results from the Phase IIb study on LixiLan showed that the fixed-ratio combination of Lyxumia[®] with Lantus[®] (insulin glargine) (2 units glargine/1 microgr lixisenatide) gave robust HbA_{1c} reduction with weight loss and no increased hypoglycemia versus Lantus[®] and with very low gastro-intestinal adverse events in Type 2 diabetes patients inadequately controlled on metformin.

At week 24, mean HbA_{1c} was reduced to 6.3% and 6.5% with LixiLan and Lantus[®] respectively, establishing statistical superiority of LixiLan, and 84%/78% achieved HbA_{1c} <7%. Body weight was reduced with LixiLan (p< 0.0001) with no increase in hypoglycemia events compared to Lantus[®], and no severe hypoglycemia. Incidence of nausea/vomiting was only 7.5%/2.5% with LixiLan.

Since January 2014, the LixiLan fixed-ratio combination of Lyxumia[®] with Lantus[®] is in Phase III development with expected US NDA submission as early as at the end of 2015.

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About Zealand

Zealand Pharma A/S (“Zealand”) (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand has leading expertise in the discovery, design and development of novel peptide medicines and a mature portfolio of therapeutic products, which are all based on internal inventions. The company’s focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its lead product is lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, marketed as Lyxumia[®] under a license agreement with Sanofi. Lyxumia[®] is approved in several countries globally, including Europe and Japan. In the US, submission of an NDA is expected in 2015, after completion of a cardiovascular outcome study, ELIXA. A once-daily single injection combination of Lyxumia[®] and Lantus[®] (LixiLan) is in Phase III development by Sanofi with planned first regulatory filing as early as at the end of 2015.

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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