

**Company announcement**

No. 25/2011

**Zealand Pharma announces new results on lixisenatide (Lyxumia<sup>®1)</sup> for Type 2 diabetes presented by Sanofi at the 21<sup>st</sup> World Diabetes Congress**

*Copenhagen, 5 December 2011* - Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL), a Danish biopharmaceutical company dedicated to the discovery and development of innovative peptide drugs, announces that new results on lixisenatide (Lyxumia<sup>®</sup>) will be presented by the company's partner Sanofi at the International Diabetes Federation's 21<sup>st</sup> World Diabetes Congress, 5 – 8 December 2011 in Dubai, United Arab Emirates. Lixisenatide is an investigational new GLP-1 agonist for once-daily dosing, discovered by Zealand Pharma and developed by Sanofi for the treatment of Type 2 diabetes.

In a poster session today at 2:00 - 3:00 pm Dubai local time (11:00 am - 12:00 noon CET), Sanofi will present three posters with titles and conclusions as follows:

*"Pharmacodynamic characteristics of lixisenatide QD<sup>2)</sup> versus liraglutide QD in patients with T2DM inadequately controlled with metformin" (Abstract D-0740)\**

Conclusion: Lixisenatide QD had a significantly greater post-prandial glucose lowering (PPG) effect than liraglutide QD in patients with Type 2 diabetes (-129% versus -41%, respectively), accompanied by significant decreases in insulin, C-peptide and glucagon and a better gastro-intestinal tolerability profile.

\* This is a 4-week Phase II study

*"Post-meal pharmacodynamic profile of lixisenatide once daily versus placebo in T2DM insufficiently controlled on SU ± metformin (GetGoal-S)" (Abstract D-0743)*

Conclusion: Add-on treatment with lixisenatide (once-daily) provided a marked significant improvement in postprandial glycemic control over 24 weeks in Type 2 diabetes patients insufficiently controlled on SU ± metformin. Lixisenatide also reduced glucagon and pro-insulin and thus improved glucose homeostasis.

The GetGoal-S study is part of the GetGoal Phase III clinical program with lixisenatide, and positive top-line results from the study were reported by Sanofi and announced by Zealand Pharma in April 2011 (Company Announcement no. 5/2011, 12 April 2011).

- 1) Lyxumia<sup>®</sup> is the intended trademark for lixisenatide
- 2) QD = once-daily dosing

*"Comparison of the Once-Daily GLP-1R Agonists Lixisenatide and Liraglutide on Prandial Carbohydrate Utilization in Animal Models" (Abstract D-0737)*

Conclusion: In the present animal studies, lixisenatide and liraglutide had a different impact on post-prandial carbohydrate utilization, with lixisenatide having a stronger prandial effect than liraglutide. This potent effect of lixisenatide on post-meal glucose control might result in improvement of glucose control in Type 2 diabetes, allowing more patients to reach their HbA1c target with body weight loss.

Further, in two oral presentations scheduled for presentation at the congress on Thursday, 8 December at 10:45-12:45 local time (7:45-9:45 CET), Sanofi will present results from two studies under the GetGoal Phase III program with lixisenatide: top-line results from the GetGoal-M study and additional results from the GetGoal-F1 study, from which study positive top-line results were reported by Sanofi at EASD 2011 and announced by Zealand Pharma mid-September 2011 (Company Announcement no. 15/2011, 12 September 2011). The two oral presentations are titled as follows:

*"Efficacy and safety of lixisenatide QD morning and evening injections versus placebo in T2DM inadequately controlled on metformin (GetGoal-M)" (Abstract O-0591)*

*"Long-term (up to 2 years) safety of lixisenatide once daily versus placebo in T2DM insufficiently controlled on metformin (GetGoal-F1)" (Abstract O-0595)*

In November 2011, the European Medicines Agency (EMA) accepted Sanofi's marketing authorization application filed for lixisenatide (Lyxumia®). Submission for regulatory approval of lixisenatide in the United States is expected in Q4 2012.

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**About lixisenatide (Lyxumia®)**

Lixisenatide, a glucagon-like peptide-1 (GLP-1) agonist for once-daily dosing, is in development for the treatment of patients with Type 2 diabetes mellitus. Lixisenatide was discovered by Zealand Pharma and has been licensed to Sanofi. Lyxumia® is the intended trademark of lixisenatide. Lixisenatide is not currently approved or licensed anywhere in the world.

GLP-1 is a naturally-occurring peptide that is released within minutes of eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate insulin secretion by pancreatic beta cells. GLP-1 receptor agonists are in development as an add-on treatment for Type 2 diabetes and their use is endorsed by the

European Association for the Study of Diabetes (EASD), the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists and the American College of Endocrinology.

The GetGoal Phase III clinical program provides data for lixisenatide in adults with Type 2 diabetes treated in monotherapy, with various oral anti-diabetic agents or in combination with basal insulin. The GetGoal program started in May 2008 and has to date enrolled more than 4,500 patients. So far top-line results have been reported for the GetGoal-X, GetGoal-L, GetGoal-L Asia, GetGoal-Mono, GetGoal-S and GetGoal-F1 studies, all supporting potential efficacy and safety for lixisenatide. Further Phase III results are expected in 2011 and 2012.

#### **About Zealand Pharma**

Zealand Pharma A/S is a public (NASDAQ OMX: ZEAL) biopharmaceutical company based in Copenhagen, Denmark with a mature and growing clinical pipeline of innovative peptide based drugs. The company's lead product is lixisenatide (Lyxumia®<sup>1)</sup>), a once-daily GLP-1 agonist for the treatment of Type 2 diabetes, discovered by Zealand Pharma and licensed to Sanofi. In November, Sanofi filed for marketing authorization for lixisenatide (Lyxumia®) in Europe. Submission for regulatory approval of lixisenatide in the U.S. is expected in Q4 2012. Zealand Pharma also has a collaboration with Boehringer Ingelheim covering glucagon/GLP-1 dual agonists, including ZP2929 for the treatment of diabetes and obesity, and a license agreement with Helsinn Healthcare on elsiglutide, a clinical stage GLP-2 drug for the treatment of chemotherapy- and radiotherapy- induced diarrhea.

Zealand Pharma specializes in the discovery, optimization and development of novel peptide drugs, and all drug candidates in its pipeline have been identified through the company's own drug discovery activities. Zealand Pharma's products target 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](http://www.zealandpharma.com).

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