Company announcement
No. 26/2011

Positive results reported by Sanofi for once-daily lixisenatide (Lyxumia® [1)]) in combination with Lantus® (insulin glargine) in Type 2 diabetes

-- Data from a Phase III study, GetGoal Duo 1, show that lixisenatide in combination with Lantus® helps achieve HbA1c <7.0% in Type 2 diabetes and significantly improves 2-hour post-prandial glucose in uncontrolled patients

Copenhagen, 6 December 2011 - Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) announces that its partner Sanofi has reported positive top-line results from a Phase III study, GetGoal Duo 1, evaluating the efficacy and safety of lixisenatide (Lyxumia®) in combination with Lantus® (insulin glargine), Sanofi's world leading basal insulin product, for the treatment of patients with Type 2 diabetes uncontrolled on oral anti-diabetic (OAD) treatment – mainly metformin. Lixisenatide is an investigational once-daily GLP-1 peptide agonist discovered by Zealand Pharma and licensed to Sanofi.

In GetGoal Duo 1, lixisenatide in combination with insulin glargine achieved the primary study endpoint of significantly reducing HbA1c with a significant improvement in 2-hour post-prandial glucose levels compared to insulin treatment alone in patients with Type 2 diabetes.

Commenting on today's announcement**, David Solomon, Chief Executive Officer and President of Zealand Pharma,** said**:** *"We are very excited about the continuous flow of strong results from the GetGoal studies, supporting the unique clinical profile of lixisenatide. The positive outcome of the GetGoal Duo 1 study provides additional important evidence for the use of lixisenatide in combination with Lantus® for the treatment of Type 2 diabetes. Lantus® is the No.1 leading basal insulin product in the world, and the results from GetGoal Duo 1 show that adding lixisenatide to treatment with Lantus® can offer significant benefits to patients."*

"Lixisenatide is a promising new GLP-1 agonist with a mode of action which complements that of basal insulin. Added once-daily to optimally titrated Lantus®, it safely improved HbA1c with beneficial effects on both post-prandial glucose and body weight," commented **Dr Matthew Riddle, Professor of Medicine and Head of the Diabetes Division at the Oregon Health and Science University, Portland, U.S.**

1) Lyxumia® is the intended trademark of lixisenatide.

''This is another key milestone in the clinical development program for our new GLP-1 agonist," declared **Pierre Chancel, Senior Vice-President of Sanofi Diabetes**. *"Achieving glycemic control and compliance with treatment is a complex challenge. These positive results show that once-daily lixisenatide in combination with Lantus® could be an innovative therapeutic option for the treatment of uncontrolled Type 2 diabetes by addressing its pathophysiology especially regarding post-prandial glucose control with a convenient once-daily regimen, helping those patients who fail to meet HbA1c target despite controlled fasting plasma glucose."*

The Phase III GetGoal Duo 1 study was a 24-week randomized, double-blind, placebo-controlled study in patients with Type 2 diabetes uncontrolled on oral anti-diabetic (OAD) treatment – mainly metformin. In a 12-week run-in period to the study, patients were initiated on insulin glargine and titrated to reach a target fasting plasma glucose of 80-100 mg/dL. After 12 weeks, 446 patients with HbA1c >7% - despite controlled fasting plasma glucose, were randomized to receive either lixisenatide once-daily or placebo while insulin glargine and metformin were continued.

During the run-in period, patients' HbA1c decreased on average from 8.60% to 7.60%. In the study period thereafter, patients randomized to treatment with lixisenatide in addition to Lantus® had a significantly greater further HbA1c decrease compared with the placebo group ($p<0.0001$) after 24 weeks to a mean value of 6.96%. A significantly higher percentage of patients in the lixisenatide arm achieved target HbA1c <7.0% compared to the placebo group (56.3% versus 38.5%, $p=0.0001$).

Lixisenatide also significantly improved 2-hour post-prandial glucose with a mean difference of -3.16 mmol/L ($p<0.0001$) vs placebo. The mean difference in body weight change between the lixisenatide and placebo groups was -0.89 kg ($p=0.0012$).

Consistent with the GLP-1 class, the most common adverse events were mild and transient nausea and vomiting. Fifty lixisenatide-treated patients (22.4%) and 30 patients (13.5%) in the placebo group reported symptomatic hypoglycemic events as defined in the protocol during the on-treatment period. 88% of patients in the lixisenatide arm reached and remained on the 20 µg maintenance dose.

On 16 November 2011, the European Medicines Agency (EMA) accepted Sanofi's marketing authorization application for lixisenatide (Lyxumia®) as submitted by Sanofi at the end of October. Submission for regulatory approval of lixisenatide in the United States is expected in Q4 2012.

The full study results from GetGoal Duo 1 are planned to be presented at a future medical congress.

Agreement with Sanofi and financial outlook

Under the license agreement between Sanofi and Zealand Pharma, Sanofi is developing lixisenatide both as a stand alone product (intended trademark Lyxumia®) in the Phase III GetGoal program and in a combination pen device with Lantus®. Zealand Pharma is eligible to receive remaining milestone payments of up to USD 235 million and low double-digit royalties on global net sales of lixisenatide and any combination product that includes lixisenatide.

The results of the GetGoal Duo 1 showing the effect and safety of lixisenatide (Lyxumia®) as add-on treatment to Lantus® do not change Zealand Pharma's financial guidance for 2011 of DKK 170 (EUR 22.8) million in revenues and other income and total operating expenses of DKK 170 (EUR 22.8) million.

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About lixisenatide (Lyxumia®)
Lixisenatide, a once-daily glucagon-like peptide-1 agonist (GLP-1), 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, the American Diabetes Association, 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 enrolled more than 4,500 patients. To date, top-line results have been reported from 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, positive top-line results have been reported from the Phase III GetGoal Duo 1 study (also known as EFC10781*) supporting in particular the efficacy and safety of lixisenatide for use in combination with Lantus® (insulin glargine) . Further Phase III results are expected in 2012.
* NCT00975286 on www.clinicaltrials.gov

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® [1)]), a once-daily GLP-1 agonist for the treatment of Type 2 diabetes, discovered by Zealand Pharma and licensed to Sanofi. In October 2011, Sanofi filed for marketing authorisation for lixisenatide (Lyxumia®) in Europe. Submission for regulatory approval of lixisenatide in the United States is planned for 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.

Note 1): Lyxumia® is the intended trademark of lixisenatide.