

**Company Announcement** 

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# Additional positive results from global Phase III program with lixisenatide for Type 2 Diabetes

# Lixisenatide achieves reduced HbA1c with a significant decrease in body weight, as an add-on therapy to sulfonylureas

- In the 859-patient GetGoal-S Phase III study, lixisenatide achieved the primary efficacy endpoint of reduced HbA1c with a significant decrease in body weight and no increase in hypoglycemia as an add-on therapy for patients with Type 2 diabetes insufficiently controlled by sulfonylureas
  - Results show potential for an improved blood glucose level during the day, further supporting the promising therapeutic profile of lixisenatide

Copenhagen, 12 April 2011 – Zealand Pharma (NASDAQ OMX: ZEAL), a biopharmaceutical company based in Scandinavia, today announced the release by its partner, sanofi-aventis, of positive top-line results from the GetGoal-S Phase III study of lixisenatide, a once-daily GLP-1 agonist in development for patients with Type 2 diabetes. In the study, lixisenatide achieved the primary efficacy endpoint of significant HbA1c reduction, improved glycemic control from baseline versus placebo and led to a significant decrease in body weight.

GetGoal-S, the largest of nine studies in the GetGoal Phase III clinical program, investigated the efficacy and safety of lixisenatide as an add-on therapy for patients with Type 2 diabetes whose condition was inadequately controlled by sulfonylureas, with or without metformin. GetGoal-S was a randomized, double-blind and placebo-controlled study with a 24-week treatment period. In the study, a total of 859 patients were randomized to receive either lixisenatide or placebo in step-wise increasing doses, up to a maintenance dose of 20µg daily.

Patients in the lixisenatide group experienced a significant reduction in their HbA1c levels, with a 0.74% difference versus placebo (p<0.0001) at week 24. Lixisenatide also significantly improved patients' 2-hour post-prandial (after meal) glucose (p<0.0001) and fasting plasma glucose (p<0.0001) levels. In addition, patients treated with lixisenatide had a significant decrease in body weight (p<0.0001), versus those receiving placebo.

Results from GetGoal-S also showed that lixisenatide did not significantly increase the risk of symptomatic hypoglycemia at week 24 (p=0.23), compared with placebo.

Commenting on today's announcement, **David Solomon**, **President and Chief Executive Officer of Zealand Pharma**, said: "We are delighted with these additional positive results on lixisenatide,

Zealand Pharma



our Type 2 diabetes drug partnered with sanofi-aventis. The GetGoal-S study is one of the largest and most important studies within the entire GetGoal Phase III program, and the significant HbA1c reduction, improved glycemic control and decrease in body weight observed in the study is a critical regulatory step. Thus, the results further demonstrate the drug's potential as an important new therapy for patients needing a more effective means of managing their Type 2 diabetes, and as a new entrant to the growing GLP-1 market. We are highly encouraged by the progress that sanofiaventis is making with this program."

In the press release from sanofi-aventis, **Pierre Chancel, Senior Vice President, Global Diabetes Division** said: "The results of GetGoal-S are another positive step for lixisenatide and reinforce the efficacy and safety profile of this new GLP-1. The demonstration of benefits in terms of improving glycemic control and reducing body weight in this population, without significantly increasing the risk of symptomatic hypoglycemia, confirmed that lixisenatide is a potential important new therapy in Type 2 diabetes to help people manage their condition more effectively."

The full study findings from the GetGoal-S study are planned to be presented at the 47th European Association for the Study of Diabetes (EASD) Annual Meeting, in September 2011.

## The agreement with sanofi-aventis and financial outlook

Under the license agreement between sanofi-aventis and Zealand Pharma, sanofi-aventis is developing lixisenatide both as monotherapy in the Phase III GetGoal programme and in a combination with Lantus<sup>®</sup>, its best selling global insulin product. Sanofi-aventis is responsible for development and commercialization of the Lixisenatide family. Zealand Pharma is eligible to receive milestone payments of up to EUR 235 million and double-digit royalties of worldwide sales of both lixisenatide as monotherapy and of combination products including lixisenatide.

The results of the GetGoal-S study do not change Zealand Pharma's financial guidance for 2011 of an operational expense of approximately DKK 170 million (EUR 22.8 million).

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#### **About Lixisenatide**

Lixisenatide, a glucagon-like peptide-1 agonist (GLP-1), is in development for the treatment of patients with Type 2 diabetes mellitus. Lixisenatide has been discovered by Zealand Pharma and in 2003, the global rights to the compound were in 2003 out-licensed to sanofi-aventis.

#### **About GLP-1 receptor agonists**

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.

#### About the GetGoal Phase III clinical program

The GetGoal phase III clinical program is providing expanding evidence for the efficacy and safety of lixisenatide in adults with Type 2 diabetes treated with various oral anti-diabetic agents or insulin. With nine trials in the program, GetGoal started in May 2008 and has enrolled more than 4300 patients. To date GetGoal-X, GetGoal-Mono, GetGoal-L Asia and GetGoal-X have reported positive top-line results supporting efficacy and safety for lixisenatide. Further results are expected during 2011.

#### **About Zealand Pharma**

Zealand Pharma A/S is a public (NASDAQ OMX: ZEAL) Scandinavian based biopharmaceutical company with a mature and growing clinical pipeline of innovative peptide drugs. The company's lead product candidate is a once-daily GLP-1 in late-stage Phase III development for the treatment of Type 2 Diabetes in collaboration with sanofi-aventis. Zealand Pharma also has several other collaboration and licensing partnerships, including a license agreement with Helsinn Healthcare on a clinical stage GLP-2 drug for the treatment of Chemotherapy and Radiotherapy Induced Diarrhoea.

Zealand Pharma has unique expertise in peptide discovery and optimization and in the development of novel peptide drugs with favourable therapeutic attributes. The company targets metabolic (diabetes and obesity), gastrointestinal and cardiovascular diseases, 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. All of Zealand Pharma's product candidates have been identified through the company's own drug discovery activities. The company is headquartered in Copenhagen and has approximately 90 employees. For more information please visit <a href="https://www.zealandpharma.com">www.zealandpharma.com</a>.