

**Company Announcement**  
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## **Positive top-line phase III data in type 2 diabetes achieved for lixisenatide once-daily vs. exenatide twice-daily**

***~ Lixisenatide meets primary efficacy endpoint with fewer hypoglycaemias ~***

Zealand Pharma A/S (NASDAQ OMX: ZEAL), a biopharmaceutical company dedicated to the discovery and development of innovative peptide drugs, is pleased to announce that its partner, sanofi-aventis, today announced that the GetGoal-X Phase III study of lixisenatide, a once-daily GLP-1 receptor agonist licensed from Zealand Pharma, achieved its primary endpoint of non-inferiority in HbA1c reduction from baseline, compared with exenatide twice-daily.

In addition, the initial results showed that significantly fewer people with type 2 diabetes treated with lixisenatide once-daily reported hypoglycemic events versus patients treated with exenatide. In the lixisenatide arm three-fold fewer people reported symptomatic hypoglycemia than people who were on exenatide (2.5% vs. 7.9%;  $p < 0.05$ ). Six-fold fewer hypoglycemia events were observed in patients on lixisenatide than those treated with exenatide (8 vs. 48 events). Other endpoints were broadly consistent with what has been observed with other GLP-1 agonists.

**Commenting on today's announcement, David Solomon, President and Chief Executive Officer of Zealand Pharma, said:** *"We are delighted that lixisenatide achieved its primary endpoint in this first Phase III head-to-head study with a marketed GLP-1 product. This is a further confirmatory step in the development and approval path for lixisenatide, lending additional support to the drug's potential role for patients with type 2 diabetes and their care providers."*

The GetGoal-X clinical trial is a randomized, open-label, active-controlled, two-arm parallel-group, multicenter study, with a 24-week main treatment period. It compared the efficacy and safety of the two GLP-1 receptor agonists: once-daily lixisenatide vs. twice-daily exenatide as add-on therapy for people with type 2 diabetes whose condition is inadequately controlled by metformin. A total of 639 people were randomized to receive either lixisenatide or exenatide. Both groups received a stepwise increase in dose, up to a maximum daily dose of 20µg.

*"GetGoal-X, the first head-to-head study comparing lixisenatide with another GLP-1, demonstrates the efficacy of lixisenatide once-daily in reducing HbA1c in people with type 2 diabetes and also shows a better hypoglycemia profile," said Pierre Chancel, Senior Vice President, Global Diabetes, sanofi-aventis, "The lixisenatide clinical development program exemplifies our commitment to people with diabetes and our ambition to help them manage their condition more effectively."*

The full study findings will be presented by sanofi-aventis at a medical congress.

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**About Zealand Pharma A/S**

Zealand Pharma is a Danish biopharmaceutical company dedicated to the discovery and development of innovative peptide drugs. The Company is based in Copenhagen and joined the NASDAQ OMX Copenhagen in November 2010 trading under the ticker symbol 'ZEAL'.

Zealand Pharma targets diseases where it believes existing treatments fail to adequately serve the medical needs of patients and the market potential for improved treatments through the use of peptide drugs is high.

Zealand Pharma focuses on three therapeutic areas: metabolic (diabetes and obesity), gastrointestinal and cardiovascular diseases. The Company's expertise in peptide discovery, optimization and development has resulted in a strong and growing pipeline of novel peptide drug candidates with favourable therapeutic attributes.

Since 1999, Zealand Pharma's scientists have built a pipeline that includes five compounds in clinical development, four of which have been out licensed, two of these with major pharmaceutical companies (sanofi-aventis and Helsinn Healthcare). All of Zealand Pharma's compounds emerged from the Company's own drug discovery.

For more information please visit the Company's web site: [www.zealandpharma.com](http://www.zealandpharma.com).

**About lixisenatide**

Lixisenatide, a glucagon-like peptide-1 agonist (GLP-1), is in development for the treatment of patients with type 2 diabetes mellitus.

The efficacy and safety of lixisenatide once-daily is being assessed in the GetGoal Phase III clinical trial program. The GetGoal clinical trial program started in May 2008 and has enrolled more than 4,500 patients globally. Enrolment of the GetGoal Phase III program assessing efficacy and safety of lixisenatide in adult patients with type 2 diabetes mellitus treated with various oral anti-diabetic agents or insulin was completed at the end of 2009. The next results of the GetGoal Phase III program are expected to be released in Q2 2011.

**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 EASD, the American Diabetes Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology.

**About diabetes and type 2 diabetes (Source: WHO)**

- More than 220 Million people worldwide have diabetes
- In 2005, an estimated 1.1 Million people died from diabetes
- Almost 80% of diabetes deaths occur in low- and middle-income countries
- Almost half of diabetes deaths occur in people under the age of 70 years; 55% of diabetes deaths are in women
- WHO projects that diabetes deaths will double between 2005 and 2030
- Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of diabetes

Type 2 diabetes results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity. Symptoms may be similar to those of type 1 diabetes, but are often less marked. As a result, the disease may be diagnosed several years after onset, once complications have already arisen. Until recently, this type of diabetes was seen only in adults but it is now also occurring in children.