Company Announcement
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Lyxumia® (lixisenatide) one-step treatment regimen as effective as two-step regimen in improving glycemic control in type 2 diabetes

- Data from GetGoal-F1, the sixth consecutive Phase III study of lixisenatide to show positive results, support a simplified once-daily dosing regimen

- Study results to be presented at the European Association for the Study of Diabetes (EASD) 47th Annual Meeting

Copenhagen, 12 September 2011 - Zealand Pharma A/S (NASDAQ OMX: ZEAL), a Danish biopharmaceutical company dedicated to the discovery and development of innovative peptide drugs, today announced that its partner Sanofi has reported positive results from the GetGoal-F1 study with Lyxumia® (lixisenatide). Lixisenatide is a once-daily GLP-1 receptor agonist discovered by Zealand Pharma and licensed to Sanofi, who is completing clinical Phase III development of the drug for type 2 diabetes.

The objectives of GetGoal-F1 were to compare the efficacy and safety of lixisenatide (20 µg once-daily) versus placebo in one-step and two-step dose increase regimens in type 2 diabetes patients uncontrolled on metformin. Lixisenatide achieved the primary efficacy endpoint of significant HbA1c reduction with both dosing regimens. Sanofi will present the study findings on Wednesday, 14 September in a poster session at the 47th Annual Meeting of the European Association for the Study of Diabetes in Lisbon, Portugal under the title:

"*Efficacy and Safety of Lixisenatide Once-Daily Versus Placebo in Patients with Type 2 Diabetes Insufficiently Controlled on Metformin (GetGoal-F1)" - ABSTRACT 784*

David H. Solomon, President and CEO of Zealand Pharma, commented:
"We are delighted to see these positive results from the GetGoal- F1 study. Of the ten studies in the global Phase III GetGoal program with lixisenatide in type 2 diabetes, six have now reported positive and consistent results to support the therapeutic relevance of this drug. We look forward to seeing the results of the remaining studies and to the filing of Lyxumia® by our partner Sanofi in Europe in Q4 this year and in the US and Japan during 2012."

The GetGoal-F1 study was a randomized, double-blind, placebo-controlled, parallel group, multicenter study with a 24-week main treatment period. A total of 482 patients with type 2 diabetes were randomized and exposed to one of the following once-daily treatment regimens: lixisenatide one-step dose increase (10µg for two weeks, then 20µg); lixisenatide two-step dose increase (10µg for one week, 15µg for one week, then 20µg), or placebo, as add-on to metformin.

Top-line results show that lixisenatide significantly reduces HbA1c from baseline to week 24 in both treatment regimens, compared with placebo (one-step: -0.92%; two-step: -0.83% vs. placebo: -0.42%; p<0.0001). The percentage of patients reaching HbA1c targets of ≤ 6.5% and < 7.0% was 25.6% and 47.4% with the one-step regimen and 20.4% and 42.1% with the two-step regimen versus 7.6% and 24.1% with placebo, respectively.

In addition, both one- and two-step regimens reduced body weight: one-step, 2.63kg (p=0.0042) and two-step, 2.68kg (p=0.0025), versus placebo, -1.63kg.

Geremia Bolli, MD, of the University of Perugia, Italy and lead investigator of the GetGoal-F1 study, said*: "The GetGoal-F1 study shows that, in people with type 2 diabetes not achieving adequate glycemic control, lixisenatide once daily as 'add on' to metformin is effective in both improving glycemic control and reducing body weight, and the one-step dose increase regimen may be the best option for treatment initiation."*

The percentage of patients who discontinued during the main 24-week treatment period due to adverse events was 5.6% in the one-step regimen, 8.1% in the two-step regimen versus 2.5% with placebo. Overall, lixisenatide was well tolerated and gastrointestinal event levels were in line with expectations for the GLP-1 class. The most frequently reported adverse events were nausea (26.1% [1-step], 35.4% [2-step] vs. 4.4% with placebo) and vomiting (11.8% [1-step], 15.5% [2-step] vs. 0% with placebo). There was no increased risk of severe hypoglycemia.

Other results for Lyxumia® (lixisenatide) presented at EASD

In addition to results from the GetGoal-F1 study, additional clinical results from the GetGoal-S and the GetGoal-X studies (positive top-line results announced for both studies earlier in 2011) will also be presented on Wednesday, 14 September at EASD under the following titles:

"Efficacy and safety of lixisenatide once-daily versus exenatide twice-daily in patients with type 2 diabetes insufficiently controlled on metformin (GetGoal-X)" - ABSTRACT 786

"Efficacy and safety of lixisenatide once-daily versus placebo in patients with type 2 diabetes mellitus insufficiently controlled on sulfonylurea +/- metformin (GetGoal-S)" - ABSTRACT 785

The agreement with Sanofi and financial outlook

Sanofi is developing lixisenatide as monotherapy (Lyxumia®) in the clinical Phase III GetGoal program and in a combination with Lantus®, its best selling global insulin product. Under the agreement with Sanofi, Zealand Pharma is eligible to receive remaining milestone payments of up to USD 235 million and low double-digit royalties of worldwide sales of both Lyxumia® and combination products including lixisenatide.

The results of the GetGoal-F1 study do not change Zealand Pharma's financial guidance for 2011 of total operating expenses of approximately EUR 23 million and revenues and other income of EUR 20 million related to the agreement with Boehringer Ingelheim (announced mid-June 2011). Zealand Pharma provides no further guidance on revenues.

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About Lyxumia® (lixisenatide)
Lixisenatide, a 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 A/S and the global rights are licensed to Sanofi. Lyxumia® is the intended trademark for 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 will provide data for lixisenatide in adults with type 2 diabetes treated with various oral anti-diabetic agents or insulin. With ten trials in the program, GetGoal started in May 2008 and has enrolled more than 4,300 patients. To date, GetGoal-X, GetGoal-L, GetGoal-L Asia, GetGoal-Mono, GetGoal-S and GetGoal-F1 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) biopharmaceutical company based in Copenhagen, Denmark with a mature and growing clinical pipeline of innovative peptide based drugs. The company's lead product is Lyxumia® (lixisenatide), a once-daily GLP-1 agonist licensed to Sanofi, which has Lyxumia® in late-stage Phase III development for the treatment of type 2 diabetes. 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 licence 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 with favorable therapeutic attributes, 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.