Company Announcement
No. 21/2012

Zealand Pharma announces that once-daily Lyxumia®[1] (lixisenatide) has received CHMP positive opinion for the treatment of adults with Type 2 diabetes in the EU

Copenhagen, 16 November 2012 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) announces that its partner, Sanofi (EURONEXT: SAN and NYSE: SNY), has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA), recommending the approval of once-daily Lyxumia® (lixisenatide) for the treatment of adults with Type 2 diabetes to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. The CHMP positive opinion will now be forwarded to the European Commission, which has the authority to approve medicines for the European Union. A formal decision by the Commission is expected in the coming months.

Lyxumia® (lixisenatide), a once-daily GLP-1 agonist with a pronounced post-prandial glucose lowering effect, was invented by Zealand Pharma and with global rights licensed to Sanofi. Sanofi has evaluated the efficacy, safety and tolerability profile of lixisenatide in the extensive global Phase III clinical trial program, GetGoal, which comprised 11 clinical trials involving more than 5,000 patients with type 2 diabetes. GetGoal included a large number of patients studied to evaluate a GLP-1 receptor agonist in combination with basal insulin (706 patients in three trials).[2]

The CHMP positive opinion is based on results from the GetGoal Phase III program, which showed that once-daily lixisenatide significantly reduced HbA1c – glycated haemoglobin – in patients with Type 2 diabetes (primary endpoint) and showed an associated significant reduction in post-prandial glucose and a beneficial effect on body weight. The GetGoal program also showed that lixisenatide was well-tolerated overall, with only mild and transient adverse effects (primarily nausea, vomiting, and diarrhea)) and a limited risk of hypoglycaemia.

Commenting on today's announcement**, David Solomon, CEO and President of Zealand Pharma, said:**
"We are very pleased by today's news that the European CHMP has given our drug invention, Lyxumia® (lixisenatide), a positive recommendation for market approval. This event may represent a watershed moment in time for Zealand Pharma, and together with our partner, Sanofi, we now look forward to a formal decision by the European Commission in the coming months. Following the CHMP positive opinion and an additional 11 regulatory applications filed for lixisenatide by Sanofi during 2012, we also await the planned filing in the US in December this year."

"We have great confidence in the therapeutic potential of lixisenatide, and in particular in the commercially strong hands of Sanofi do we expect this new once-daily GLP-1 drug to provide a substantial added benefit to the global management of Type 2 diabetes."

In a press release from Sanofi today, **Pierre Chancel, Senior Vice-President, Global Diabetes at Sanofi, commented;**
"The CHMP positive opinion for Lyxumia marks an important milestone in the development of this compound and brings us one step closer to serving even more patients by expanding the Sanofi Diabetes product portfolio. This recommendation validates our belief that Lyxumia, a once-daily GLP-1 receptor agonist with a pronounced post-prandial glucose lowering effect, is a promising medicine that can be combined with other treatments, such as basal insulin, to help patients with Type 2 diabetes achieve target HbA_{1c} levels. We look forward to receiving the European Commission decision."

In addition to the European Union, lixisenatide has been submitted for regulatory approval in 11 countries. Submission of a New Drug Application to the United States Food and Drug Administration (FDA) is planned for December 2012.

Financial guidance for 2012 and the terms of the Sanofi agreement
As earlier announced, there is no milestone payment to Zealand Pharma associated with an approval of lixisenatide in Europe, and Zealand Pharma retains its financial guidance for 2012. As presented in the Interim Report for the first nine months of 2012 (Company Announcement no. 20/12 of 13 November 2012) the company guide for revenues of DKK 224 (EUR 30) million with related royalty expenses of DKK 16 (EUR 2) million and a positive net result for the year of DKK 30-40 (EUR 4-5) million.

Under the agreement between Sanofi and Zealand Pharma, Zealand Pharma is eligible to receive remaining development and sales milestone payments of up to USD 215 million, including USD 40 million for a depot formulation of lixisenatide. Further, the company is entitled to tiered low double-digit percentage royalties on global net sales of lixisenatide and fixed low double-digit percentage royalties on full net sales of lixisenatide-Lantus® combination products.

References

1. Lyxumia is the proprietary name submitted to the EMA for lixisenatide. The proprietary name for lixisenatide in the United States is under consideration. Lixisenatide is not currently approved or licensed anywhere in the world.
2. http://clinicaltrials.gov/ct2/results?term=GetGoal. Date accessed: October 2012

# # #

For further information, please contact:

David H. Solomon, President and Chief Executive Officer
Tel: +45 2220 6300

Hanne Leth Hillman, Vice President and Head of IR & Corporate Communication
Tel: +45 5060 3689, email: hlh@zealandpharma.com

About lixisenatide (Lyxumia®)
Lixisenatide (Lyxumia®) is a once-daily GLP-1 receptor agonist, invented by Zealand Pharma, and developed under a global license partnership with Sanofi for the treatment of patents with Type 2 diabetes, both as a stand-alone product and in a fix-flex combination pen with Lantus® (insulin glargine), Sanofi's world-leading basal insulin product. The global GetGoal Phase III clinical program provides data for lixisenatide (Lyxumia®) 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 enrolled more than 5,000 patients, with results serving as support for applications for regulatory approval of lixisenatide as a stand-alone product
Phase III studies of a lixisenatide and Lantus® combination product in a fix-flex pen device allowing for flexible Lantus dosing with a fixed lixisenatide dose are planned for start in mid-2013.

About GLP-1 receptor agonists

GLP-1 (glucagon-like peptide-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 to stimulate insulin secretion by pancreatic beta cells. GLP-1 receptor agonists are members of an established class of diabetes drugs approved by regulatory authorities and marketed globally as an add-on treatment for patients with Type 2 diabetes. 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. Several novel GLP-1 receptor agonists are in development.

About Diabetes

Diabetes is a chronic disease that occurs as Type 1 diabetes, which is a genetic autoimmune disease characterized by the lack of insulin (the hormone that regulates blood glucose concentrations) production by the pancreas, and Type 2, a metabolic disorder in which there are two main biological defects: a deficient production of insulin and reduced ability of the body to respond to the insulin being produced. Type 1 and Type 2 diabetes are characterised by an increase in blood glucose concentrations (hyperglycaemia). Over time, uncontrolled hyperglycaemia leads to the macrovascular and microvascular complications of diabetes. Macrovascular complications, which affect the large blood vessels, include heart attack, stroke and peripheral vascular disease. Microvascular complications affect the small blood vessels of the eyes (retinopathy), kidney (nephropathy) and nerves (neuropathy).

More than 18 million people worldwide are living with Type 1 diabetes, and the incidence of Type 2 diabetes is growing at an alarming rate, with nearly 348 million people worldwide living with the condition today.[1]

1. IDF Diabetes Atlas, 5th Edition (2012)

About Zealand Pharma

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand Pharma specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company's focus lies in the field of diabetes/metabolic diseases, and its lead drug invention is lixisenatide (Lyxumia®), a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. In November 2012, lixisenatide was given a CHMP positive opinion in Europe and a regulatory filing in the United States is expected in December 2012.

Zealand Pharma has a partnering strategy for the development and commercialization of its products and in addition to the collaboration with Sanofi in type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Abbott in acute kidney injury and Helsinn Healthcare in chemotherapy induced diarrhea. Zealand Pharma focuses its activities in 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

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services and devices, including innovative blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with type 1 or type 2 diabetes. Investigational compounds in the pipeline include an injectable GLP-1 receptor agonist being studied as a single agent, in combination with basal insulin, and/or in combination with oral anti-diabetic agents.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY)