Company Announcement - No. 33 / 2015

Sanofi has announced that the first LixiLan Phase III trial, LixiLan-O, met primary study endpoint

- **The LixiLan GLP-1/basal insulin combination showed statistically superior lowering of average blood glucose (HbA1c) compared with lixisenatide (Lyxumia®) and compared with insulin glargine (Lantus®) in Type 2 diabetes patients treated with metformin**
- **Following analysis of results from both the LixiLan-O and the LixiLan-L Phase III trials, expected later in Q3 2015, Sanofi will determine the next regulatory steps for LixiLan with submission currently planned for Q4 2015 in the US and Q1 2016 in Europe**
- **With the successful completion of LixiLan-O, Zealand remains on track towards expected LixiLan associated milestone payments and royalty revenue based on potential future regulatory submissions and approvals of the product**

Copenhagen, 29 July 2015 – Zealand announces that Sanofi has today reported the successful completion of LixiLan-O, one of two trials comprising the pivotal Phase III development program for LixiLan as a novel treatment for patients with Type 2 diabetes. LixiLan is a new once-daily single injection of the fixed-ratio combination of lixisenatide (Lyxumia®), a Zealand-invented once-daily prandial GLP-1 receptor agonist, and Sanofi's insulin glargine (Lantus®), the worldwide most prescribed basal insulin.

In the LixiLan-O trial, LixiLan (fixed-ratio combination of lixisenatide and insulin glargine 100 units/mL) met the primary study objective of showing a statistically superior reduction in HbA1c (three months average blood glucose) compared with lixisenatide and compared with insulin glargine 100 units/mL. Overall, LixiLan had a safety profile similar to those of lixisenatide and insulin glargine 100 units/mL. LixiLan-O enrolled 1,170 patients with Type 2 diabetes, insufficiently controlled on metformin alone or on metformin plus a second oral anti-diabetic agent. The patients were randomized to 30 weeks of treatment with either LixiLan, lixisenatide or insulin glargine, while treatment with metformin was continued for all participants throughout the study. Sanofi will communicate full results from the LixiLan-O trial at an appropriate scientific forum.

Commenting on the results of LixiLan-O, Britt Meelby Jensen, President and CEO at Zealand, said: *"These first Phase III conclusions confirm the therapeutic relevance of LixiLan and support the product's potential as a new single-injection combination treatment for patients with Type 2 diabetes.*

This is an important event indicating that LixiLan remains on track towards planned regulatory submissions by Sanofi in the US in Q4 2015 and in the EU in Q1 2016 – and that Zealand remains on track towards potential milestone payments and royalty revenues, envisaged under our license agreement with Sanofi. I now look forward to the completion of the full Phase III program with results from the LixiLan-L trial later in Q3 and to Sanofi's next regulatory steps."

The LixiLan Phase III clinical development program, initiated by Sanofi in January 2014, includes also the LixiLan-L trial. LixiLan-L investigates the efficacy and safety of LixiLan in Type 2 diabetes patients whose blood glucose levels are not adequately controlled on insulin glargine (Lantus®) alone. This trial has enrolled and treated 736 patients, and Sanofi expects to report results later in Q3 2015. Based on the combined results of the LixiLan-O and LixiLan-L trials, Sanofi will determine the next steps in the regulatory process. Currently, regulatory submissions are planned for Q4 2015 in the United States and Q1 2016 in the European Union.

Financial guidance for 2015 and terms of the license agreement with Sanofi

The successful completion of the LixiLan-O trial does not change Zealand's financial guidance for 2015, which includes expected milestone payments from license partners of up to DKK 140 million (EUR 19 million).

Under the global license agreement with Sanofi, covering lixisenatide (Lyxumia®) and any combination products which include lixisenatide, Sanofi is responsible for all development and commercialization including the financing, while Zealand is eligible to receive progress driven milestone payments and royalties on global sales. Remaining milestone payments amount to up to USD 160 million, while royalty payments correspond to tiered, low double-digit percentages of Sanofi's global sales of Lyxumia® plus fixed low double-digit percentages of global full net sales of LixiLan.

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About Zealand Pharma

Zealand Pharma A/S ("Zealand") (Nasdaq Copenhagen: ZEAL) is a biotechnology company with world leading expertise in the identification, design and development of novel peptide-based medicines, with competences spanning also in-house clinical trial design and management. The company is advancing a proprietary pipeline of novel medicines alongside a partnered product and development portfolio and with its therapeutic focus on metabolic diseases and acute care indications.

Zealand's first invented medicine, lixisenatide, is a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, which is marketed globally (ex-US) as Lyxumia® under a license agreement with Sanofi, covering also LixiLan, a new fixed-ratio combination of lixisenatide and insulin glargine (Lantus®) in Phase III development. US regulatory filing for lixisenatide is planned for Q3 2015 and filing for LixiLan is planned for Q4 2015 in the US and Q1 2016 in the EU..

The proprietary pipeline include danegaptide (prevention of Ischemic Reperfusion Injury) in Phase II and the stable glucagon analogue, ZP4207 in two clinical programs; as a single-use rescue pen (severe hypoglycemia) in preparation for Phase II and a multiple-dose version (mild to moderate hypoglycemia) in Phase I as well as several preclinical peptide therapeutics.

Zealand currently has global license agreements and collaborations with Sanofi, Helsinn Healthcare and Boehringer Ingelheim.

Zealand is based in Copenhagen, Denmark. For further information: www.zealandpharma.com Follow us on Twitter @ZealandPharma