Company announcement - No. 40 / 2015

Sanofi has announced the successful completion of LixiLan-L, the second pivotal Phase III trial with LixiLan to demonstrate positive results

- **LixiLan showed statistically superior reduction in HbA1c (average blood glucose over the previous three months) compared with insulin glargine (Lantus®) in patients with Type 2 diabetes**
- **With positive results from now two pivotal trials, LixiLan-O and LixiLan-L, regulatory submissions of LixiLan remain on track for Q4 2015 in the US and Q1 2016 in Europe**

Copenhagen, 14 September 2015 - Zealand announces that Sanofi today reported a positive study outcome of LixiLan-L, a pivotal Phase III clinical trial with LixiLan for the treatment of Type 2 diabetes.

LixiLan is a fixed-ratio single-injection combination of Sanofi's insulin glargine 100 units/mL (Lantus®), the world-wide most prescribed basal insulin, and lixisenatide. Lixisenatide is a prandial GLP-1 receptor agonist, invented by Zealand, and marketed globally outside the US by Sanofi as Lyxumia® for the treatment of Type 2 diabetes. Incorporated also in LixiLan, lixisenatide is a very important product in Zealand's portfolio of outlicensed products and projects, which are advancing alongside the company's growing proprietary pipeline of novel peptide medicines.

In the LixiLan-L trial, LixiLan successfully met the primary study endpoint of demonstrating a statistically superior reduction in HbA1c (average blood glucose over the previous three months) compared with insulin glargine 100 units/mL. Overall, LixiLan had a safety profile reflecting those of insulin glargine 100 units/mL and lixisenatide.

Commenting on the positive outcome of the LixiLan-L trial, **Britt Meelby Jensen, President and CEO of Zealand,** said: "*With positive results now demonstrated in two pivotal Phase III trials, the planned regulatory submissions of LixiLan by Sanofi before year-end in the US and next year in Europe remain on track. It is our belief that the LixiLan fixed-ratio combination of our invented medicine, lixisenatide, with insulin glargine has the potential to offer patients with Type 2 diabetes a new valuable type of treatment – for use both after failure of oral medication, and when basal insulin alone does not provide sufficient blood sugar control. The revenue prospects from LixiLan are important for Zealand to help support the advance and accelerated value creation of our proprietary pipeline.*"

LixiLan-L investigated the efficacy and safety of LixiLan versus treatment with insulin glargine 100 units/mL over a 30 week period in 736 patients whose Type 2 diabetes was not adequately controlled at screening on basal insulin, alone or combined with one to two oral anti-diabetic agents. Treatment with metformin, if previously taken, was continued throughout the study.

In July 2015, Sanofi announced the positive outcome of the first pivotal Phase III trial, LixiLan-O. In the LixiLan-O trial, LixiLan showed a significant reduction in HbA1c over a 30 week period in 1,170 patients whose Type 2 diabetes was not adequately controlled on metformin alone or on metformin combined with a second oral anti-diabetic agent.

Sanofi plans to communicate the full results of both LixiLan-O and LixiLan-L at a future scientific forum.

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

The successful completion of the LixiLan-L trial does not change Zealand's financial guidance for 2015, which includes expected milestone payments from license partners of up to DKK 155 million (EUR 21 million).

Under the global license agreement with Sanofi, covering lixisenatide (Lyxumia®) and LixiLan, Sanofi is responsible for all development and commercialization including the financing, while Zealand is eligible to receive event driven milestone payments and royalties on global sales. Remaining milestone payments amount to up to USD 160 million (EUR 141 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 (Nasdaq Copenhagen: ZEAL) ("Zealand") is a medicinal biotech company with leading expertise in the identification, design and development of novel peptide medicines. Zealand has a proprietary pipeline of novel drug candidates and a portfolio of products and projects under license collaborations with Sanofi, Helsinn Healthcare and Boehringer Ingelheim – primarily in the fields of cardio-metabolic diseases and acute care indications.

The proprietary pipeline includes danegaptide for ischemic reperfusion Injuries in Phase II development and the stable glucagon analogue, ZP4207 in two clinical development programs; as a single-dose rescue pen for severe hypoglycemia and as multiple-dose use for the correction of mild to moderate hypoglycemia in preparation and evaluation, respectively for next clinical phase after Phase I trials, as well as several preclinical peptide therapeutics.

Zealand has invented lixisenatide, a once-daily prandial GLP-1 agonist, which is marketed globally (ex-US) by Sanofi for the treatment of Type 2 diabetes. Sanofi submitted lixisenatide for regulatory approval in the US in late July 2015, and has a combination of lixisenatide with insulin glargine (Lantus®) which is on track for regulatory submission in the US in Q4 2015 and in Europe in Q1 2016.

The company is based in Copenhagen (Glostrup), Denmark. For further information about Zealand's business and activities, please visit: www.zealandpharma.com or follow us on Twitter @ZealandPharma