

Zealand reports Lyxumia® royalty revenue for Q3 2015 and that Sanofi confirms expected next steps in the US regulatory process

- **Royalty revenue to Zealand from Sanofi's sales of Lyxumia® (lixisenatide) ex-US amounted to DKK 7.1 million / EUR 0.9 million in Q3 2015, a 20% increase over Q3 2014**
- **A US regulatory decision on lixisenatide by the FDA is expected in Q3 2016**
- **Sanofi expects regulatory submission of LixiLan in Q4 2015 in the US and in Q1 2016 in Europe**

Copenhagen, 29 October 2015 – Zealand announces that royalty revenue on Sanofi's global sales of Lyxumia® (lixisenatide) ex-US amounted to DKK 7.1 million / EUR 0.9 million for the period 1 July to 30 September 2015. This corresponds to an increase of 20% over the same period in 2014. Royalties were at the same level as for the previous quarter, after an increase of 12% from the first to the second quarter in 2015. Royalty revenue for the first nine months of 2015 amounted to DKK 20.5 million / EUR 2.7 million, which corresponds to an increase of 46% compared to the same period in 2014.

Lixisenatide is a once-daily prandial GLP-1 receptor agonist for the treatment of Type 2 diabetes, invented by Zealand, developed and commercialized by Sanofi under a global license agreement. Lixisenatide is approved outside the US under the tradename Lyxumia® and the product is currently available for patients in 40 countries with further launches planned later in 2015.

In September 2015, the Food and Drug Administration (FDA) accepted for filing Sanofi's New Drug Application (NDA) for lixisenatide in the US, and a regulatory decision is expected in Q3 2016.

For LixLan, the fixed-ratio combination of lixisenatide and insulin glargine (Lantus®) for Type 2 diabetes, Sanofi expects to submit for regulatory approval in Q4 2015 in the US and in Q1 2016 in Europe.

In a comment to this announcement, Britt Meelby Jensen, President and CEO at Zealand, said:

"Lixisenatide is an important product in Zealand's portfolio, in particular combined with insulin glargine in the LixiLan combination product. We value our license collaboration with Sanofi, which today has re-confirmed the important expected next steps in the regulatory process for lixisenatide in the US and for LixiLan in the US and in Europe."



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

Zealand maintains its financial guidance for 2015, including increasing lixisenatide royalty revenue and expected milestone payments from license partners of up to DKK 155 million (EUR 21 million). Full year net operating expenses are expected to be at a range of DKK 225-235 million (EUR 30-32 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 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 (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, *ZP1848* for Short Bowel Syndrome in Phase II development and the stable glucagon analogue, *ZP4207* as a *single-dose rescue pen* for severe hypoglycemia in preparation for Phase II, and *ZP4207* as *multiple-dose use* for the correction of mild to moderate hypoglycemia in evaluation for the next clinical development step after Phase I, 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 and since end September 2015 has been under review by the FDA in the US. The license agreement with Sanofi also covers a fixed-ratio combination of lixisenatide and 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