



## Lixisenatide (Lyxumia<sup>®</sup>) royalty revenue increased in Q2 2015 as Sanofi confirms the submission of a NDA in the US

- Royalty revenue to Zealand from Sanofi's ex-US sales of lixisenatide (Lyxumia<sup>®</sup>) amounted to DKK 7.1 million (EUR 1.0 million) in Q2 2015, a 65% increase over Q2 2014
- Sanofi has in late July 2015 submitted a New Drug Application (NDA) for lixisenatide to the Food and Drug Administration (FDA) for regulatory approval in the US

Copenhagen, 30 July 2015 – Zealand announces that royalty revenue to the company on Sanofi's global sales of lixisenatide (Lyxumia<sup>®</sup>) ex-US amounted to DKK 7.1 million (EUR 1.0 million) for the period 1 April to 30 June 2015. This corresponds to an increase of 65% over the same period in 2014 and an increase of 12% over the previous quarter. Royalty revenue for the first half of 2015 amounted to DKK 13.4 million (EUR 1.8 million).

Lixisenatide is a once-daily prandial GLP-1 receptor agonist for the treatment of Type 2 diabetes, invented by Zealand and developed and commercialized by Sanofi under a global license agreement. Lixisenatide is approved under the tradename Lyxumia<sup>®</sup> in more than 50 countries ex-US and, so far, Sanofi has launched the product in more than 40 of these countries with further launches planned later in 2015.

In Sanofi's Q2 2015 earnings release today, it was confirmed that in late July, a New Drug Application (NDA) for lixisenatide was submitted to the US Food and Drug Administration (FDA) for regulatory approval of the product for treatment of Type 2 diabetes.

**In a comment to this announcement, Britt Meelby Jensen, President and CEO at Zealand, said:**  
*"We are very pleased to see the continued progress of lixisenatide (Lyxumia<sup>®</sup>). Royalty revenue to Zealand is growing, based on increasing ex-US sales of the product and the submission by Sanofi for regulatory approval in the US is particularly important. The US represents over two-thirds of the USD 3 billion GLP-1 world market, and the application increases visibility for the potential of lixisenatide US revenue generation. It also further validates the quality of Zealand's science, an essential element in our continued build-up of a proprietary pipeline of peptide therapeutics."*



## 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 140 million (EUR 19 million). Full year net operating expenses are expected at a range of DKK 225-235 million (EUR 30-32 million).

Under the global license agreement with Sanofi, covering lixisenatide (Lyxumia<sup>®</sup>) 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<sup>®</sup> plus fixed low double-digit percentages of global full net sales of LixiLan.



### For further information, please contact:

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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 portfolio of products and development projects under license collaborations - and with a therapeutic focus in the fields of 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<sup>®</sup> under a license agreement with Sanofi, covering also LixiLan, a new fixed-ratio combination of lixisenatide and insulin glargine (Lantus<sup>®</sup>) in Phase III development. Lixisenatide was submitted for regulatory approval in the US in late July 2015, and filings for LixiLan are 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](http://www.zealandpharma.com) and follow us on Twitter @ZealandPharma.