Company announcement – No. 2 / 2016

Zealand reports lixisenatide (Lyxumia®) royalty revenue for Q4 2015 and highlights three key regulatory events for the product in 2016 as confirmed by Sanofi

- **Royalty revenue to Zealand from Sanofi's sales of lixisenatide (Lyxumia®) outside the US increased to DKK 8.1 million / EUR 1.1 million in Q4 2015, up 15% over the previous quarter and up 31% over Q4 2014**
- **For the full year 2015, lixisenatide (Lyxumia®) royalty revenue amounted to DKK 28.6 million / EUR 3.8 million**
- **Three regulatory events are expected for lixisenatide in 2016:**
  1) **EU submission of the fixed-ratio combination of lixisenatide and insulin glargine 100 Units/mL (LixiLan) confirmed by Sanofi for Q1**
  2) **US regulatory decision on lixisenatide in Q3**
  3) **US regulatory decision on the fixed-ratio combination of lixisenatide and insulin glargine 100 Units/mL (LixiLan) in Q3 provided FDA accepts the filing**

Copenhagen, 9 February 2016 – Zealand reports that royalty revenue to the company on Sanofi's global sales of lixisenatide (Lyxumia®) for the treatment of Type 2 diabetes outside the US amounted to DKK 8.1 million / EUR 1.1 million for the fourth quarter period from 1 October to 31 December 2015. This corresponds to an increase of 31% over the same period in 2014. Compared to the third quarter of 2015, royalties were up 15%, which is a significant pick-up in the quarterly growth rate.

For the full year 2015, royalty revenue to Zealand thus totaled DKK 28.6 million / EUR 3.8 million, which corresponds to an increase of 41% over 2014.

In a comment to this announcement, Britt Meelby Jensen, President and CEO at Zealand, said: *"It is nice to see a relatively strong pick-up in our lixisenatide royalty revenues in Q4 2015. Still, however, the revenue level reflects the fact that the product is not yet available for patients in the US, which represents more than 70% of the world market for this type of medicine. We are therefore excited about the prospects of important regulatory decisions by the US FDA on lixisenatide in Q3 this year and in particular, if the file is accepted, on the combination product of lixisenatide and Lantus® later in the same quarter. Pending regulatory approvals, US launch of these two products are planned by Sanofi for H2 2016 and could lead to a considerable increase in Zealand's revenue."*

Lixisenatide is a once-daily prandial GLP-1 receptor agonist for the treatment of patients with Type 2 diabetes, invented by Zealand. Global development and commercialization rights are licensed to Sanofi who markets the product as Lyxumia® in 50 countries outside the US. In September, the Food and Drug Administration (FDA) accepted Sanofi's New Drug Application (NDA) for lixisenatide in the US for regulatory review. Based on a standard review process of 10 months, a US regulatory decision on lixisenatide can be expected in Q3 2016.

Sanofi has also developed a fixed-ratio combination of lixisenatide and insulin glargine 100 Units/mL (brand name Lantus®), being referred to as LixiLan. Lantus® is the most prescribed basal insulin worldwide. On 23 December 2015, it was announced by Zealand and Sanofi, respectively, that Sanofi had submitted a New Drug Application (NDA) for the combination product to the FDA for regulatory review in the US, redeeming a Priority Review Voucher (PRV) in the process. The PRV has the potential to reduce the standard FDA review process from ten to six months, indicating a possible regulatory decision in Q3 2016, if the NDA is accepted. In Sanofi's Q4 2015 earnings release today, the planned submission of LixiLan for regulatory approval in Europe in Q1 2016 has been confirmed.

Financial guidance for 2015 and 2016 and terms of the license agreement with Sanofi

Zealand financial guidance for 2015 includes increasing lixisenatide royalty revenue and expected milestone payments from license partners of up to DKK 155 million (EUR 21 million), both of which has been realized. Zealand will announce its 2015 full year results and annual report on 16 March 2016, in which connection the company will also give financial guidance for 2016.

Under the terms of the license agreement between Sanofi and Zealand, which covers lixisenatide and any combination product that includes lixisenatide, Sanofi is responsible for all development and commercialization including the financing, while Zealand is eligible to receive milestone payments and royalties on global sales. Remaining milestone payments to Zealand amount to up to USD 140 million. Royalties correspond to tiered, low double-digit percentages of Sanofi's global sales of lixisenatide (Lyxumia®) plus a fixed low double-digit percentage of global full net sales of the combination product with Lantus® (LixiLan).

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About Zealand Pharma

Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) ("Zealand") is a biotech company with leading-edge scientific expertise in turning peptides into medicines. Zealand has a growing proprietary pipeline of novel specialty drug candidates and a mature portfolio of products and projects under license collaborations with Sanofi, Helsinn Healthcare and Boehringer Ingelheim.

Zealand's first invented medicine, lixisenatide, a once-daily prandial GLP-1 analogue for the treatment of Type 2 diabetes, is marketed globally (ex-US) as Lyxumia® by Sanofi and under regulatory review in the US. The license agreement with Sanofi covers also LixiLan, which is a single-product combination of lixisenatide and insulin glargine 100 Units/mL (Lantus®). LixiLan has been submitted for regulatory priority review in the US and regulatory submission in the EU is expected in Q1 2016.

The proprietary pipeline includes; *danegaptide* for ischemic reperfusion Injuries (Phase 2); *ZP1848* for Short Bowel Syndrome (Phase 2); and the *stable glucagon analogue, ZP4207* for single-dose use in a rescue pen for severe

hypoglycemia (Phase 2) and for multiple-dose use to improve glucose control in diabetes (Phase 1); *ZP2929* for diabetes/obesity (Phase 1); and several preclinical peptide therapeutics.

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