Company announcement – No. 13 / 2016

Zealand reports Lyxumia® royalty revenue for Q1 2016 and submission by Sanofi of the fixed-ratio combination of insulin glargine (Lantus®) and lixisenatide for European registration

- **Royalty revenue to Zealand from Sanofi's sales of Lyxumia® (lixisenatide) amounted to DKK 6.5 million / EUR 0.9 million in Q1 2016**
- **In March 2016, Sanofi submitted as planned the fixed-ratio combination of basal insulin glargine (Lantus®) and lixisenatide for regulatory approval in Europe**
- **Three important US regulatory events are expected in the next four months:**
  - **25 May: FDA Advisory Committee hearing and recommendation on both lixisenatide and the fixed-ratio combination of insulin glargine and lixisenatide**
  - **July: Expected regulatory decision by the FDA on lixisenatide**
  - **August: Expected regulatory decision by the FDA on the fixed-ratio combination of insulin glargine and lixisenatide**

Copenhagen, 29 April 2016 – Zealand reports that royalty revenue to the company from Sanofi's global sales of Lyxumia® (lixisenatide) outside the US amounted to DKK 6.5 million / EUR 0.9 million for the period from 1 January to 31 March 2016. This corresponds to an increase of 3% over the same period in 2015. In its Q1 2016 earnings release today, Sanofi reported that sales of Lyxumia® grew 12.5% annually, measured at constant exchange rates.

Sanofi also confirmed that in March 2016, the fixed-ratio combination of basal insulin glargine (Lantus®) and lixisenatide, a novel investigational medicine for the treatment of adults with type 2 diabetes was submitted as planned for regulatory approval in Europe.

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

"We are pleased by the double-digit growth of sales of Lyxumia® outside the US as reported by Sanofi for Q1 2016. Important to note is that the US represents approximately 75% of the USD 4 billion global GLP-1 market and currently experiences the highest growth rate for this product class. Consequently, the FDA regulatory decision regarding lixisenatide, which is anticipated in July, will be an important factor for the expected further growth in our royalty revenue for this product.

"It is also good news that Sanofi as planned has filed for regulatory approval in Europe for the fixed-ratio combination of Lantus® and lixisenatide. For this product in the US, we look forward to the FDA Advisory Committee hearing scheduled for 25 May and the subsequent FDA regulatory decision, which is expected in August. With three key regulatory events anticipated, we have some very important months ahead of us."

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, which markets the product as Lyxumia® in more than 50 countries outside the US, excluding France and Germany. In September 2015, 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 time of 10 months, a US regulatory decision on lixisenatide is anticipated in July 2016.

Sanofi has also developed an investigational fixed-ratio combination of its worldwide most-prescribed basal insulin glargine (Lantus®) and lixisenatide. In February 2016, the FDA accepted Sanofi's NDA for the combination product for a prioritized regulatory review time of six months. Accordingly, a regulatory decision by the FDA is anticipated in August 2016.

In March 2016, the FDA announced that an Endocrinologic and Metabolic Drugs Advisory Committee meeting will be held on 25 May 2016 to review the NDAs for the investigational fixed-ratio combination of basal insulin glargine and lixisenatide and lixisenatide as an investigational new prandial GLP-1 receptor agonist and component in the combination product.

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About Zealand Pharma

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

The company's first invented medicine, lixisenatide, a once-daily prandial GLP-1 analogue for the treatment of type 2 diabetes, is licensed to Sanofi who markets the product globally (ex-US) as Lyxumia® and has it under regulatory review in the US. The license agreement with Sanofi covers also a fixed-ratio combination of lixisenatide and basal insulin glargine (Lantus®), which is under regulatory review in both the US and Europe.

Zealand's proprietary pipeline includes: *ZP4207 (single-dose*) for severe hypoglycemia (Phase II); *ZP1848* for Short Bowel Syndrome (Phase II); *ZP4207 (multiple-dose version)* for better hypoglycemia management in diabetes (Phase I); *ZP2929* for diabetes/obesity (Phase I); 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