Company announcement – No. 19 / 2016

Zealand announces that the FDA Advisory Committee voted for US approval of iGlarLixi, the fixed-ratio combination of lixisenatide and Lantus®

- **The members of the Advisory Committee voted 12-2 for an approval of iGlarLixi**
- **Both lixisenatide and iGlarLixi for the treatment of type 2 diabetes were discussed at the Advisory Committee meeting. The FDA had not requested a vote on lixisenatide**
- **FDA regulatory decisions on lixisenatide and iGlarLixi are expected in July and August 2016, respectively**
- **Zealand reiterates its financial guidance for 2016, including expectations of increasing royalty revenue and additional milestone revenue of DKK 200 million / EUR 27 million**

Copenhagen, 26 May 2016 – Zealand announced today that the Endocrinologic and Metabolic Drugs Advisory Committee of the US Food and Drug Administration (FDA) has discussed lixisenatide and iGlarLixi for the treatment of adults with type 2 diabetes. Following the discussions, the Advisory Committee members voted 12 to 2 (with 1 non-vote) to recommend approval of the New Drug Application (NDA) for iGlarLixi in the US. The Advisory Committee was not asked by the FDA to vote on the approval of the NDA for lixisenatide.

Lixisenatide is a once-daily prandial GLP-1 receptor agonist, invented by Zealand with global development and commercial rights licensed to Sanofi. IGlarLixi is a fixed-ratio combination of lixisenatide and basal insulin glargine 100 Units/mL (marketed as Lantus®), developed by Sanofi under the license agreement with Zealand. The NDAs for both products are undergoing regulatory review and a decision by the FDA is expected for lixisenatide in July 2016 and for iGlarLixi in August 2016.

In a comment, Britt Meelby Jensen, Chief Executive Officer of Zealand, said: *"I am very pleased that the FDA Advisory Committee so clearly has recommended an approval of iGlarLixi in the US as a new treatment for adults with type 2 diabetes. This positive outcome, and the supportive conclusion on lixisenatide as a stand-alone therapy, have taken us an important step closer to potentially having two medicines based on a Zealand invention being available on the US market later this year."*

She continued: "*The prospect of growing royalty revenue from lixisenatide and iGlarLixi is an important element in the execution of our strategy of building a portfolio of proprietary Zealand products to support accelerated value creation. Our portfolio includes ZP1848, a novel GLP-2 analog, which is in Phase II development for short bowel syndrome, and ZP4207, a glucagon in Phase II as a single-dose version for severe hypoglycemia in diabetes and in preparation for Phase II as a multiple-dose version*

for use in a dual-hormone artificial pancreas device. All programs are advancing as planned and we look forward to updating the market on further news in the coming months."

Sanofi's NDA for iGlarLixi is based on data from two Phase III clinical trials, LixiLan-O and LixiLan-L. The trials enrolled in total more than 1,900 adults with type 2 diabetes to evaluate the efficacy and safety of the fixed-ratio combination of basal insulin glargine 100 Units/mL and lixisenatide when used in patient populations insufficiently controlled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively. Both trials met their primary endpoints for efficacy, showing a significant reduction in HbA1c (a measure of average blood sugar levels over the previous three months) compared to treatment with either lixisenatide or Lantus® alone. The full results of both LixiLan-O and LixiLan-L are scheduled for presentation on Sunday, 12 June 2016 at the American Diabetes Association's 76th Scientific Sessions in New Orleans.

The NDA for lixisenatide is based on results from the GetGoal Phase III clinical program, which included 13 clinical trials involving more than 5,000 adults with type 2 diabetes. The NDA also includes findings from ELIXA, a long-term cardiovascular (CV) outcomes study in over 6,000 adults with type 2 diabetes and high CV risk (*i.e.,* patients who have recently experienced a spontaneous acute coronary syndrome event).

The proprietary names for both lixisenatide and iGlarLixi in the US are under consideration.

Financial guidance for 2016

Following the positive recommendation by the FDA Advisory Committee for US approval of iGlarLixi, Zealand retains its financial guidance for 2016. This includes expectations of potential royalty revenue on sales of lixisenatide and iGlarLixi in the US, pending FDA approvals, and expected additional milestone revenue of DKK 200 million / EUR 27 million.

Terms of the license agreement with Sanofi

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. Zealand is eligible to receive remaining milestone payments of up to USD 140 million / EUR 126 million and royalties on global sales. 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 net sales of the iGlarLixi combination product.

For further information, please contact:

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About FDA Advisory Committee meetings
FDA Advisory Committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendations, but it takes its advice into consideration when reviewing new drug applications.

About lixisenatide and the fixed-ratio combination of lixisenatide and insulin glargine
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. In the US, lixisenatide is under regulatory review by the Food and Drug Administration.

The lixisenatide/Lantus® combination is an investigational single-injection, fixed-ratio combination of lixisenatide and insulin glargine for the treatment of Type 2 diabetes. Insulin glargine is marketed globally by Sanofi as Lantus®.

About Zealand Pharma A/S
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 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 with basal insulin glargine (Lantus®) undergoing regulatory review in both the US and Europe.

Zealand's proprietary pipeline of product candidates includes: *ZP4207 (single-dose rescue treatment*) for acute, 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