Company announcement – No. 17 / 2016

Zealand announces FDA's posting of briefing documents for the Advisory Committee meeting on lixisenatide and the lixisenatide/Lantus® combination product on 25 May 2016

- **The briefing documents posted on FDA's website include results from the two Phase III trials with the lixisenatide/Lantus® combination, not previously published**
- **US regulatory decisions on lixisenatide and the lixisenatide/Lantus® combination are expected in July and August 2016, respectively**

Copenhagen, 23 May 2016 – Zealand announces that the US Food and Drug Administration (FDA) today has made briefing documents on lixisenatide and the lixisenatide/Lantus® combination available on its website. The documents relate to the upcoming meeting of the Endocrinologic and Metabolic Drugs Advisory Committee, scheduled by the FDA for 8:00 am to 5:00 pm ET on 25 May 2016 to discuss the New Drug Applications (NDAs) for the two drug products intended for the treatment of adults with Type 2 diabetes. The NDAs were submitted by Sanofi.

The briefing documents contain the key points for discussion at the Advisory Committee meeting and background information on lixisenatide and the lixisenatide/Lantus® combination. This include the results from Sanofi's two clinical Phase III trials with the lixisenatide/Lantus® combination, LixiLan-L and LixiLan-O, which have not previously been published. The briefing documents can be accessed under the following link:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm491062.htm

Lixisenatide is a once-daily GLP-1 receptor agonist, invented by Zealand and with global development and commercial rights licensed to Sanofi. The lixisenatide/Lantus® combination is a fixed-ratio combination of lixisenatide and basal insulin glargine (100 U/mL), developed by Sanofi under the license agreement with Zealand.

Sanofi submitted the US NDA on lixisenatide in July 2015 and it was accepted by the FDA for regulatory review in September 2015. A regulatory decision on lixisenatide is expected in July 2016. In December 2015, Sanofi submitted the US NDA on the lixisenatide/Lantus® combination product, redeeming a Priority Review Voucher with the submission. In February the FDA accepted the NDA for priority review with a regulatory decision expected in August 2016.

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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 recommendation, 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. No US tradename has been decided for lixisenatide.

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®) under 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