Company announcement – No. 32 / 2016

Zealand announces new timelines for a U.S. FDA decision on iGlarLixi, the fixed-ratio combination of lixisenatide (Adlyxin™) and Lantus®, for the treatment of type 2 diabetes

- **The FDA had requested updated information on the pen delivery device for iGlarLixi as part of its New Drug Application, which has been submitted by Sanofi**
- **Consequently, the FDA has extended their review time by three months**
- **A regulatory decision on iGlarLixi in the U.S. is now expected at the end of November 2016**
- **Zealand's financial guidance for 2016 remains unchanged**

Copenhagen, 20 August 2016 – Zealand Pharma (Zealand) announced today that Sanofi has submitted updated information on the pen delivery device for iGlarLixi to the U.S. Food and Drug Administration (FDA) as part of the New Drug Application (NDA) for the product. IGlarLixi is a once-daily, fixed-ratio combination of lixisenatide (Adlyxin™) and insulin glargine 100 Units/mL (Lantus®) for the treatment of adults with type 2 diabetes. The submission of the additional information, requested by the FDA, constitutes a Major Amendment to the NDA, resulting in an extension of the Prescription Drug User Fee Act (PDUFA) goal date by three months. A U.S. regulatory decision on iGlarLixi is now expected before the end of November 2016.

Zealand invented lixisenatide, a once-daily prandial GLP-1 receptor agonist, for the treatment of type 2 diabetes and granted global development and commercial rights to the product, including for use in combinations, to Sanofi. On 27 July 2016, lixisenatide was approved by the U.S. FDA under the brand name Adlyxin™ for the treatment of adults with type 2 diabetes. Lixisenatide is approved and marketed globally by Sanofi outside the U.S. under the brand name Lyxumia®.

Sanofi submitted the NDA for iGlarLixi to the FDA in December 2015, and on 25 May 2016, the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the FDA recommended, by a vote of 12 to 2, its approval.

Britt Meelby Jensen, President and Chief Executive Officer of Zealand commented:
"The extension of FDA's review time for iGlarLixi by three months to November 2016 is related to a request for additional information on the pen device. IGlarLixi is a combination of two already FDA approved diabetes medicines and has in clinical trials demonstrated significant benefits for adults with type 2 diabetes. The combination received a convincing positive recommendation for approval by an FDA advisory committee in May, and Sanofi believes that the additional information submitted will result in an offering that will serve the patient needs."

Sanofi submitted the fixed-ratio combination of lixisenatide (Adlyxin™/Lyxumia®) and basal insulin glargine 100 Units/mL (Lantus®) for regulatory review by the European Medicines Agency (EMA) in March 2016. A regulatory decision is expected in Q1 2017.

Financial guidance for 2016 remains unchanged

The extension of the FDA review time for Sanofi's NDA for iGlarLixi in the U.S. by three months does not change Zealand's financial guidance for 2016.

For further information, please contact:

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About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a portfolio of medicines and product candidates under license collaborations with Sanofi, Boehringer Ingelheim and Helsinn and a pipeline of proprietary product candidates, which primarily target specialty diseases with significant unmet needs.

The company's first invented medicine, lixisenatide, a once-daily prandial GLP-1 analog for the treatment of type 2 diabetes, is licensed to Sanofi. Lixisenatide is marketed as Lyxumia® outside the United States and approved as Adlyxin™ in the United States. Lixisenatide has been developed in a fixed-ratio combination with Lantus® (insulin glargine) which product is under regulatory review in the United States and in Europe.

Zealand's proprietary pipeline includes: *Dasiglucagon* (ZP4207) as single-dose rescue treatment* for acute, severe hypoglycemia (Phase II); *ZP1848* for treatment of short bowel syndrome (Phase II); *Dasiglucagon* (ZP4207) multiple-dose version* intended for use in a dual-hormone artificial pancreas system for better hypoglycemia control and diabetes management (in preparation for Phase II); and other earlier stage clinical and preclinical peptide therapeutics.

Zealand is based in Copenhagen (Glostrup), Denmark. For further information about the company's business and activities, please visit www.zealandpharma.com or follow Zealand on Twitter @ZealandPharma.

* Dasiglucagon is a proposed International Nonproprietary Name (pINN).