Company announcement – No. 29 / 2016

FDA approves lixisenatide as Adlyxin™ for the treatment of adults with type 2 diabetes in the U.S.

- **Approval paves the way for launch by Sanofi of the first Zealand invented product in the U.S.**
- **Triggers a $5 million milestone payment from Sanofi**
- **FDA is currently reviewing iGlarLixi, the fixed-ratio combination of Adlyxin™ (lixisenatide) and Lantus® (insulin glargine), with regulatory decision expected in August 2016**
- **Zealand is eligible to receive remaining milestone payments of up to $135 million as well as royalties on global sales**

Copenhagen, 28 July 2016 – Zealand Pharma (Zealand), a biotechnology company, announces that the U.S. Food and Drug Administration (FDA) has granted approval of lixisenatide for the treatment of adults with type 2 diabetes. Lixisenatide, a once-daily prandial GLP-1 receptor agonist, was invented by Zealand and global development and commercial rights are licensed to Sanofi.

Lixisenatide has been approved in the U.S. under the brand name Adlyxin™ indicated as an adjunct to diet and exercise for the treatment of adults with type 2 diabetes, including in combination with oral anti-diabetes medication and/or basal insulin. There are an estimated 27.5 million adults with type 2 diabetes (American Diabetes Association, 2012) in the U.S., and the U.S market constitutes approximately 75% of the world market for GLP-1 receptor agonists (IMS, 2016).

Britt Meelby Jensen, President and Chief Executive Officer of Zealand commented:
"Today is an important day for Zealand. With the FDA approval of Adlyxin™ we have successfully passed the final regulatory milestone for the first Zealand invented product to become available for diabetes patients in the significant U.S. market. We look forward to Sanofi's launch of Adlyxin™, while awaiting the FDA's regulatory decision on iGlarLixi, the single product combination of Adlyxin™ and Lantus®, expected in August 2016."

The FDA approval of Adlyxin™ (lixisenatide) was based on review of the results from Sanofi's worldwide GetGoal clinical program and from the ELIXA trial, which successfully addressed the FDA's request to demonstrate cardiovascular safety for the product. The GetGoal program evaluated the safety and efficacy of lixisenatide in 13 clinical trials, involving more than 5,000 adults with type 2 diabetes. All trials in the GetGoal program successfully achieved the primary efficacy endpoint of blood glucose (HbA1c) reduction. Consistent with what has been seen for other GLP-1 receptor agonists, the most common adverse events reported for lixisenatide included nausea, hypoglycemia and vomiting.

Sanofi will make Adlyxin™ available for patients in a disposable pre-filled injection pen for once-daily doses of 20 micrograms. For the first 14 days of treatment, patients will receive a disposable pre-filled pen for once-daily doses of 10 micrograms before transitioning to 20 micrograms once daily.

Lixisenatide is approved under the proprietary name, Lyxumia®, in more than 60 countries outside the U.S. and marketed by Sanofi in over 40 of these. Commercial launches include most EU countries, Japan, Brazil, Mexico and India.

Sanofi has also developed iGlarLixi, the fixed-ratio combination of Adlyxin™ (lixisenatide) and Lantus® (insulin glargine 100 Units/mL), its worldwide most-prescribed basal insulin. iGlarLixi is undergoing FDA review with a regulatory decision expected in August 2016.

Financial guidance for 2016

The approval of lixisenatide (Adlyxin™) by the U.S. FDA triggers a milestone payment of $5 million / €4.6 million to Zealand from Sanofi, payable in Q3 2016.

Subsequently, Zealand reiterates its financial guidance for 2016, including expectations of U.S. royalty revenue on sales of Adlyxin™ and potentially on iGlarLixi, pending FDA approval, as well as expected total milestone revenue of DKK 200 million / €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 $135 million as well as royalties on global sales. Royalties correspond to tiered, low double-digit percentages of Sanofi's global sales of lixisenatide (Lyxumia®/Adlyxin™) plus a fixed low double-digit percentage of global net sales of iGlarLixi.

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About Adlyxin™

Adlyxin™ (lixisenatide) is an analog of the glucagon-like peptide-1 (GLP-1) receptor agonist (GLP-1 RA) for the once-daily treatment of adult patients with type 2 diabetes as an adjunct to diet and exercise. GLP-1 is a native peptide hormone that is released within minutes after eating a meal. It is known to stimulate glucose-dependent insulin release by pancreatic beta cells and suppress glucagon secretion from pancreatic alpha cells. Adlyxin™ increases glucose-dependent insulin release, decreases glucagon secretion, and slows gastric emptying.

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 pipeline of proprietary product candidates which primarily target specialty disease areas with significant unmet medical needs and a portfolio of medicines and product candidates under license collaborations with Sanofi, Boehringer Ingelheim and Helsinn.

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. Lixisenatide is marketed globally outside the United States as Lyxumia® and approved in the U.S. as Adlyxin™. A fixed-ratio combination of lixisenatide with insulin glargine (Lantus®), referred to as iGlarLixi, is under regulatory review in the U.S. and in Europe.

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

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