**Company announcement – No. 2/2017**

# EU approval of Suliqua™ triggers USD 10 million milestone payment to Zealand

- **Suliqua™ approved in the EU for treatment of adults with type 2 diabetes**
- **Approval triggers a milestone payment of USD 10 million to Zealand**
- **Sanofi plans to launch Suliqua™ in individual EU countries from Q2 2017 onward**

*Copenhagen, 17 January 2017* – Zealand Pharma (Zealand) today announced a USD 10 million milestone payment following Sanofi's announcement of European Commission (EC) marketing authorization in Europe for Suliqua™, the once-daily titratable fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide for the treatment of adults with type 2 diabetes. Suliqua™ is authorized for use in combination with metformin to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin.[1]

**Britt Meelby Jensen, President and Chief Executive Officer of Zealand, comments:**
*"We welcome the approval by the European Commission of Suliqua™ in the EU. The product will be marketed by Sanofi and the first launch is planned for Q2 2017. We look forward to see this treatment option made available to people with diabetes in the EU, helping to achieve glycemic control without increasing the risk of hypoglycemia and without additional weight gain. Following the recent launch of Soliqua™100/33 in the U.S., this is another important milestone for us, which will provide significant revenue to Zealand in many years to come."*

The approval is based on data from two phase III studies, LixiLan-O and LixiLan–L, which enrolled more than 1,900 adults with type 2 diabetes worldwide to evaluate the efficacy and safety of the fixed-ratio combination when used in patient populations insufficiently controlled after OADs or after basal insulin therapy.

Suliqua™ is the brand name in Europe for the once-daily titratable fixed-ratio combination of basal insulin glargine 100 units/ml and the GLP-1 analogue lixisenatide. Suliqua™ will be delivered in two pre-filled SoloSTAR® pens, providing different dosing options that may help answer individual market and patient insulin needs.

Marketing authorization in Europe for Suliqua™ is applicable to the 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway, and follows the November 2016 positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The fixed-ratio combination was approved by the U.S. Food and Drug Administration (FDA) in November 2016, as Soliqua™ 100/33, and has been available in the U.S. since 4 January, 2017. Launches in individual EU countries are anticipated from Q2 2017 onward.

[1] Suliqua™ EU Summary of Product Characteristics, 2017.

## 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 financing hereof.

The EU approval of Suliqua™ triggers a milestone payment of USD 10 million to Zealand. Under the agreement, Zealand is eligible to receive remaining milestone payments of up to USD 100 million as well as low double-digit percentages on global sales in royalty income.

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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 that primarily target specialty diseases with significant unmet needs.

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 as Adlyxin™ in the U.S and Lyxumia® in the rest of the world. Lixisenatide has been developed in a fixed-ratio combination with basal insulin glargine (Lantus®) and is marketed as Soliqua™ 100/33 in the U.S. and approved as Suliqua™ in Europe.

Zealand's pipeline includes: dasiglucagon* (ZP4207, single-dose rescue treatment) for acute, severe hypoglycemia (phase II); glepaglutide* (ZP1848) for 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 (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 and glepaglutide are proposed International Nonproprietary Names (pINN).