Company announcement – No. 46 / 2016

The U.S. FDA approves Soliqua™ 100/33 for the treatment of adults with type 2 diabetes

- **FDA approval triggers a $25 million milestone payment and double-digit percentage royalties of net sales of Soliqua™ to Zealand**
- **Sanofi plans to make Soliqua™ available in U.S. retail pharmacies in January 2017**
- **Zealand management will host a teleconference on Tuesday 22 November at 4pm CET**

Copenhagen, 22 November 2016 – Zealand Pharma (Zealand) announced today that Sanofi has received U.S. Food and Drug Administration (FDA) approval for Soliqua™ 100/33 (insulin glargline and lixisenatide injection) 100 Units/mL and 33 mcg/mL for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 Units daily) or lixisenatide (Adlyxin™).

Soliqua™ 100/33 will be delivered in a single pre-filled pen for once-daily dosing covering 15 to 60 Units of insulin glargine 100 Units/mL and 5 to 20 mcg of lixisenatide using SoloSTAR® technology, the most frequently used disposable insulin injection pen platform in the world.[1] Soliqua™ 100/33 will be available in U.S. retail pharmacies in January 2017.

Britt Meelby Jensen, President and Chief Executive Officer of Zealand commented:
"I am very excited about FDA's approval of Soliqua™. The fixed-ratio combination of Lantus® and lixisenatide is a new drug, that has proven to outperform its individual components. The U.S. approval of Soliqua™ comes only 10 days after CHMP recommended approval of Suliqua™ in the EU, making November 2016 one of the most important months in the history of Zealand. Together with lixisenatide, which was approved in the U.S. in July this year under the brand name Adlyxin™, we expect substantial revenue growth in the years to come. This gives us the financial strength to deliver on our strategy to develop our own product candidates, glepaglutide and dasiglucagon all the way to registration".

Elias Zerhouni, M.D., President, Global R&D, Sanofi commented:
"Sanofi continues to be a pioneer in developing diabetes therapies and in bringing forward new treatment options for the approximately 50 percent of patients whose blood sugar levels remain uncontrolled on daily basal insulin. Soliqua 100/33 is an alternate new approach that can help adults living with type 2 diabetes uncontrolled on basal insulin or lixisenatide to reach their treatment goal. "

Soliqua™ 100/33 is the combination of Lantus® (insulin glargine 100 Units/mL) and lixisenatide, a GLP-1 receptor agonist, in a once-daily injection, studied in a Phase 3 program of more than 1,900 patients. In an insulin intensification study, Soliqua™ 100/33 showed better HbA1c (average blood sugar over time) lowering versus Lantus® with a majority of the 736 patients (55% vs. 30%) achieving the American

[1] Data on file: IMS Q_Global Q4/2015, V.Kircher

Diabetes Association target of less than 7% at 30 weeks. Patients treated with Soliqua™ 100/33 experienced similar rates of documented (≤70 mg/dL) hypoglycemia compared to Lantus®-treated patients.

CHMP positive opinion recommending Suliqua™ in the EU

Earlier in November, Sanofi received a positive opinion from the Committee for Medicinal Product for Human Use (CHMP) of the European Medicines Agency (EMA) recommending approval of Suliqua™ (brand name in Europe). A formal decision by the European Commission is expected in the coming months. Once approved, Sanofi will make Suliqua™ available in the EU in two pre-filled SoloSTAR® pens (10–40 SoloSTAR® pen and 30–60 SoloSTAR® pen).

Conference call on Tuesday, 22 November 2016 at 4 pm CET / 10 am EDT

Zealand's senior management will host a conference call Tuesday, 22 November at 4 pm CET to give an update on the implications for Zealand. Participating in the call will be Britt Meelby Jensen, President and Chief Executive Officer, Mats Blom, SVP and Chief Financial Officer and Adam Steensberg, SVP and Chief Medical and Development Officer. The presentation will be followed by a Q&A session.

The conference call will be conducted in English and the dial-in numbers are:

DK standard access	+45 32 71 16 60
UK and international	+44 (0) 20 3427 1919
U.S. (free dial-in)	+1 646 254 3362

Kindly inform the operator of the following passcode: "Zealand Pharma" or 4119215.

A live audio webcast of the call including an accompanying slide presentation will be available via the following link, http://edge.media-server.com/m/p/ykcwu3fn accessible also from the company's website (www.zealandpharma.com). Participants are advised to register for the webcast approximately 10 minutes before the start.

A replay of the event will be made available from the Investor section of Zealand's website following the call.

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.

The approval of Soliqua™ by the U.S. FDA triggers a milestone payment of $25 million to Zealand from Sanofi. Zealand is eligible to receive remaining milestone payments of up to $110 million as well as royalties on global sales. Royalties correspond to tiered, low double-digit percentages of Sanofi's global sales of Adlyxin™/Lyxumia® plus a fixed low double-digit percentage of global net sales of Soliqua™/Suliqua™.

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About Soliqua™

Soliqua™ is a once-daily, titratable fixed-ratio combination of lixisenatide GLP-1 receptor agonist (Adlyxin™/Lyxumia®) and basal insulin glargine 100 units/ml (Lantus®) for the treatment of adults with type 2 diabetes.

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 licence 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 analogue 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 basal insulin glargine (Lantus®) and is approved as Soliqua™ in the United States, and in Europe a CHMP positive opinion recommendation was given on 11 November. Suliqua™ is the brand name in Europe.

Zealand's proprietary pipeline includes: Dasiglucagon* (ZP4207) (single-dose rescue treatment) for acute, severe hypoglycaemia (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 hypoglycaemia 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 and Glepaglutide are proposed International Nonproprietary Names (pINN).