Company Announcement – No. 1 / 2017

Zealand reports that Sanofi announces Soliqua™ 100/33 now available in the U.S

- **Soliqua™ 100/33 is now available by prescription in U.S. pharmacies by Sanofi**
- **In December 2016, Zealand received the $ 25 million milestone payment triggered by the FDA approval of Soliqua 100/33**

Copenhagen, 4 January 2017 – Zealand Pharma (Zealand) reports that Sanofi announced today that Soliqua™ 100/33 (insulin glargine 100 Units/mL & lixisenatide 33 mcg/mL injection) is now available by prescription in U.S. pharmacies. Soliqua 100/33 is indicated for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 Units daily) or lixisenatide.

Adlyxin™ (lixisenatide), the once daily prandial GLP-1 analogue invented by Zealand and approved by the FDA in July 2016, is also available by prescription in U.S. pharmacies.

Britt Meelby Jensen, President and Chief Executive Officer of Zealand commented:

"*We are excited that these new treatment options are broadly available to U.S. patients, for Soliqua 100/33 only six weeks after approval. Soliqua 100/33, a product containing both a basal insulin and a GLP-1 therapy, has demonstrated superior HbA1c lowering versus Lantus. It will be marketed by Sanofi and I am very pleased to see their strong commitment to the launch as well as their approach to reduce potential pricing barriers for Soliqua 100/33 in the U.S. The latter is critical in today's U.S. market environment, in order for as many patients as possible to get access the medication they need to manage their diabetes."*

In the labeled clinical trial, once-daily Soliqua 100/33 demonstrated statistical superiority for the change in HbA1c from baseline to week 30 ($p<0.0001$) versus Lantus®, the most prescribed basal insulin in the world.[1,2,3]. Soliqua 100/33 is delivered in a single pre-filled SoloStar pen with a dose range covering from 15 to 60 Units and two starting doses to support patients' insulin needs. Soliqua 100/33 was approved by the U.S. Food and Drug Administration (FDA) on 21 November, 2016.

The Wholesale Acquisition Cost (WAC) price of Soliqua 100/33 is $127 for a 300 Unit pen, which equals $19.90 per day at the average final dose of 47 Units used in the labeled clinical trial.

Sanofi is offering Soliqua 100/33 at a $0 co-pay** for eligible U.S. patients with commercial insurance and is working to secure coverage for Soliqua 100/33 on health plans nationwide.

CHMP positive opinion recommending Suliqua™ in the EU

In November 2016, 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 this quarter and will trigger a $ 10 million milestone payment to Zealand. 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).

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 FDA approval of Soliqua 100/33 by the U.S. FDA triggered a milestone payment of $ 25 million to Zealand, which was received in December 2016 as planned. 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 100/33 / Suliqua™.

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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 licence 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 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™ 100/33 in the United States, while 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 (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).

References

1. Data on file: IMS Q_Global Q4/2015, V.Kircher.
2. Rosenstock J, et al. Presentation 186-O presented at American Diabetes Association (ADA) 76th Scientific Sessions, New Orleans, LA, U.S., 2016. Available from Date accessed: November 2016.
3. Aroda V, et al. Presentation 238-O presented at American Diabetes Association (ADA) 76th Scientific Sessions, New Orleans, LA, U.S., 2016. Available from Date accessed: November 2016.

** With the SOLIQUA 100/33 Savings Card, patients may be eligible for the $0 CO-PAY offer for the next 12 months. Restrictions apply. This offer is for commercially insured patients and is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, or TRICARE, or similar federal or state programs including any state pharmaceutical programs. Void where prohibited by law. Savings card carries maximum savings of $700 off per pack for the duration of the program. Savings may vary depending on patient's out-of-pocket costs. Upon registration, patient receives all program details. Sanofi US reserves the right to rescind, revoke, or amend the program without notice.