

Company Announcement
No. 1/2014

Zealand announces advance by Sanofi of LixiLan, the single injection Lyxumia[®]/Lantus[®] combination product, towards Phase III development and a related milestone payment

- The first LixiLan Phase III study protocol has now been approved, triggering a USD 15 million payment to Zealand from Sanofi***
- This milestone is in line with recently updated plans by Sanofi to start Phase III development in Q1 2014***

Copenhagen, 15 January 2014 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) (“Zealand”) announces that under its license agreement with Sanofi (EURONEXT: SAN and NYSE: SNY) covering Lyxumia[®] (lixisenatide) and any combination product including lixisenatide, a milestone has been achieved in the advance of LixiLan, the once-daily single injection Lantus[®] (basal insulin) / Lyxumia[®] (lixisenatide) combination product, towards start of Phase III development in the 1st quarter of 2014. The milestone relates to the approval of the first Phase III study protocol for LixiLan by a Health Authority, triggering a USD 15 million payment to Zealand.

Lixisenatide is a once-daily prandial GLP-1 receptor agonist invented by Zealand for the treatment of Type 2 diabetes. Worldwide development and commercial rights to the product are exclusively licensed to Sanofi.

The announced first LixiLan Phase III study protocol approval follows an update provided by Sanofi yesterday at the Annual J.P. Morgan Healthcare Conference, held in San Francisco, on the status of Lyxumia[®] and LixiLan. As part of the update, Sanofi confirmed plans to start Phase III development of LixiLan in the 1st quarter of 2014, narrowing its earlier guidance of an expected start in H1 2014.

Further to this, in their presentation, Sanofi also confirmed that Lyxumia[®] is being introduced progressively in a larger number of countries as a new once-daily prandial GLP-1 agonist therapy for patients with Type 2 diabetes. In addition to its pronounced effect on lowering meal related glucose (post-prandial glucose, PPG), Lyxumia[®] has a beneficial effect on body weight and is associated with a limited risk of hypoglycemia. This profile makes Lyxumia[®] particularly well suited for use as add-on therapy to basal insulin, including Lantus[®].



Welcoming the announced milestone of LixiLan Phase III advance and the update from Sanofi, **David Solomon, Chief Executive Officer of Zealand Pharma, said:** *“We are very pleased to be able to share this important and confirmatory milestone of the first LixiLan Phase III protocol approval. This news is fully in line with Sanofi’s expectations to start Phase III development in the 1st quarter of 2014. Zealand believes that the combination of Lyxumia® with Lantus®, Sanofi’s blockbuster product and the worldwide leading basal insulin, into one single device has an exciting potential, in our view also adding to the validation of the therapeutic relevance of Lyxumia®, the first Zealand invented product on the market.”*

Financial outlook

The milestone payment of USD 15 million from Sanofi will positively impact on Zealand’s financial results for 2014. Zealand will provide its financial outlook for 2014 in connection with the issuance of the company’s Full Year announcement and Annual Report for 2014 on 20 March 2014.

Under the license agreement with Sanofi, covering lixisenatide (Lyxumia®) and any combination products including lixisenatide, Zealand is eligible to up to USD 160 million in remaining milestones. Further, Zealand will receive tiered low double-digit percentage royalties on Sanofi’s global sales of Lyxumia® and fixed low double-digit percentage royalties on global full net sales of the Lyxumia®/Lantus® combination product.

For further information, please contact:

David H. Solomon, President and Chief Executive Officer

Tel: +45 2220 6300

Hanne Leth Hillman, Vice President and Head of IR & Corporate Communications

Tel: +45 5060 3689, email: hlh@zealandpharma.com



About Zealand

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) (“Zealand”) is a biotechnology company based in Copenhagen, Denmark. Zealand specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company’s focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its lead drug invention is lixisenatide, a once-daily prandial GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide (marketed by Sanofi as Lyxumia®) is approved in several countries, including Europe and Japan, and under regulatory review in a number of other countries globally. In the U.S., an NDA is planned to be submitted in 2015, after completion of the ELIXA Cardiovascular outcome study.

Zealand has a partnering strategy for the development and commercialization of its products and in addition to the license agreement with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Lilly in diabetes and obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury.

For further information: www.zealandpharma.com

 @ZealandPharma