Company Announcement
No. 16/2013

Zealand informs of commercial and regulatory status updates provided by Sanofi on Lyxumia® for Type 2 diabetes

− and of plans announced by Sanofi to start Phase III studies of the Lantus®/Lyxumia® combination product in H1 2014

— In Germany, where Lyxumia® was first marketed, the product has gained >8% share of the GLP-1 agonist market only three months after launch by Sanofi

— Lyxumia® is marketed also in the UK and Scandinavia, and further European roll-out by Sanofi is ongoing

— Regulatory decision on Lyxumia® in Japan expected mid-2013

— The commercial attractiveness for Lyxumia® further validates Zealand's peptide drug competences

Copenhagen, 24 June 2013 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") informs that Sanofi (SANF.PA) today provided an update on the status for Lyxumia® and the Lantus®/Lyxumia® combination product. Lyxumia® (lixisenatide), the first once-daily prandial GLP-1 agonist for the treatment of adults with Type 2 diabetes, is a Zealand discovered peptide drug. Worldwide rights to develop and sell lixisenatide are exclusively licensed to Sanofi, covering also its use in combination treatments, including combinations with Lantus®, Sanofi's leading diabetes product and the world's most prescribed basal insulin product.

In an IR Thematic Conference Call on Diabetes, held by Sanofi today at 2pm CET (7am CDT) during the American Diabetes Association's (ADA's) 73rd Scientific Sessions in Chicago, updates were given on the status and outlook for Lyxumia® and the Lantus®/Lyxumia® combination product, including the following:

- Phase III studies of the Lantus®/Lyxumia® combination product will be initiated with first patient dosing expected in H1 2014. Results from a Phase IIb study support Sanofi's 'Go'-decision for Phase III.
- In March 2013, Lyxumia® was launched in Germany, and the product has gained 8.1% share of the GLP-1 market after only three months on the market.

- Lyxumia® has been marketed also in the UK and Scandinavia, and Sanofi is continuing the roll-out of Lyxumia® progressively throughout Europe.
- A regulatory decision on the NDA submitted for Lyxumia® in Japan (June 2012) is expected by mid-2013.
- Enrollment of up to 6,000 patients in ELIXA, a randomized, double-blind, placebo-controlled global multicenter study to evaluate cardiovascular outcomes during treatment with lixisenatide in Type 2 diabetic patients after an Acute Coronary Syndrome, expected to complete in 2013. Interim data from ELIXA is being evaluated by the FDA as part of the regulatory data package submitted for Lyxumia® in the US. Final ELIXA results are expected towards the end of 2014.

Commenting on the news and the implications for Zealand, **Zealand's Chief Executive Officer, David Solomon, said**:

"We are very pleased that Lyxumia® as a Zealand invented peptide medicine is being well received by patients and their caregivers. Lyxumia® is the first prandial GLP-1 agonist for once-daily dosing being introduced to the market, and we look forward to following its continued commercial progress by Sanofi, one of the world's top-leading diabetes companies – expected to lead to important revenues for Zealand. The specific profile of Lyxumia® makes it well-suited for combination treatment with basal insulin, and the prospects of the Lantus®/Lyxumia® combination product to enter Phase III development to potentially offer to patients additional therapeutic value of combination therapy in a single product is highly promising. Sanofi has announced their plans to move this program into Phase III, which will represent an important milestone for Zealand to support our continued efforts to innovate, design and develop novel peptide medicines for the benefit of patients."

Financial outlook for 2013 and terms of the agreement with Sanofi

The update on Lyxumia® and the new development timelines given for the Lantus®/Lyxumia® combination product does not change the 2013 financial outlook for Zealand as announced by the company in its Interim report for Q1 2013 on 15 May 2013 (Company Announcement no. 14/2013).

Under the license agreement with Sanofi, Zealand is entitled to up to a total of USD 275 million in milestone payments, of which up to potentially USD 175 million are outstanding. 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 Lantus®/Lyxumia® combination product.

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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, including diabetes and obesity, and its lead drug invention is lixisenatide, a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide is approved and launched (March 2013) in Europe under the name of Lyxumia®, and under regulatory review in a large number of other countries globally, including in the US (NDA submission accepted in Feb 2013) and Japan (NDA filed in June 2012).

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

For further information: www.zealandpharma.com.

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