

Company Announcement
No. 12/2014

Zealand reports increased Lyxumia[®] royalty revenue for H1 2014 and informs of status update as provided by Sanofi

- *Lyxumia[®] royalty revenue to Zealand increased to DKK 8.2 (EUR 1.1) million in H1 2014. Excluding Germany, this is an increase of 125% over H2 2013*
- *Continued roll-out of Lyxumia[®] by Sanofi in Europe, Emerging Markets and Rest of the World with several new launches in Q2 2014 and further expected for the rest of 2014*
- *In the US, resubmission of a New Drug Application is planned for Summer 2015 after completion of the ELIXA cardiovascular outcome study in H1 2015*

Copenhagen, 31 July 2014 – Zealand Pharma A/S (“Zealand”) (NASDAQ OMX Copenhagen: ZEAL) reports Lyxumia[®] royalty revenues of DKK 8.2 (EUR 1.1) million in the first half of 2014 based on Sanofi’s global ex-US sales of the product for the period. This corresponds to an increase of 125% compared to the royalty revenue for the second half of 2013, when excluding Germany, where Sanofi, on 1 April 2014, withdrew the product from the market following the outcome of price negotiations under AMNOG law.

Since the first European market launch in March 2013, Sanofi has been rolling-out Lyxumia[®] commercially ex-US with the product now available in an increasing number of countries in Europe, Emerging Markets and Rest of the World exclusive of the US. In June 2014, the German arbitration board set a new reimbursement level for Lyxumia[®]. On the basis of this decision, Lyxumia[®] remains unavailable in Germany.

In a comment to the royalty revenue report and the status update on Lyxumia[®], **David Solomon, President and CEO of Zealand**, said:

“We are pleased to see Sanofi’s continued commercial roll-out of Lyxumia[®] globally outside the US and the growing contribution of sales royalties to our revenue. Together with Sanofi, we are confident of the value Lyxumia[®] can bring to patients and believe it has the profile to become an important product in the GLP-1 landscape. As more than 80% of the market is in the US, we are looking forward to the expected resubmission by Sanofi of Lyxumia[®] to the FDA in mid-2015.”

Sanofi is conducting a large Cardiovascular Safety Outcome Trial with Lyxumia[®], the ELIXA study, where the target enrolment of 6,000 Type 2 diabetes patients has been completed. The



results are expected in the first half of 2015 and to lead to the resubmission by Sanofi of a New Drug Application for Lyxumia® in the US in mid-2015.

In parallel, Sanofi is conducting Phase III studies with LixiLan, a fixed-ratio combination of Lyxumia® with Lantus®, the world's most widely prescribed basal insulin. These studies are expected to complete in the second half of 2015 and with planned regulatory submission of LixiLan as early as the end of 2015.

Financial outlook for 2014

For 2014, Zealand expects revenue from milestone payments of DKK 133 (EUR 18). Further, the company receives revenue in the form of Lyxumia® sales royalties, which amounted to DKK 8.2 (EUR 1.1) million for the first half of the year. No guidance can be provided for the level of royalty revenues for the full year as Sanofi has given no guidance on sales.

Full year net operating expenses are expected at a range of DKK 195-205 (EUR 25-28) million.

Zealand will announce its Interim Report for the first half of 2014 on 21 August 2014.

Under the license agreement with Sanofi, covering lixisenatide (Lyxumia®) and any combination products including lixisenatide, Zealand is eligible to remaining milestone payments of up to USD 160 million. Further, Zealand is entitled to 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 LixiLan combination product.

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About Zealand Pharma

Zealand Pharma A/S ("Zealand") (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand has leading expertise in the discovery, design and development of novel peptide medicines and a mature portfolio of therapeutic products, which are all based on internal inventions. The company's focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its



lead product is lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, marketed as Lyxumia® under a license agreement with Sanofi. Lyxumia® is approved in several countries globally, including Europe and Japan. In the US, submission of an NDA is expected in 2015, after completion of a cardiovascular outcome study, ELIXA. A once-daily single injection combination of Lyxumia® and Lantus® (LixiLan) is in Phase III development by Sanofi with planned first regulatory filing as early as at the end of 2015.

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 two collaborations with Boehringer Ingelheim in diabetes/obesity and cardio-metabolic diseases, one with Lilly in diabetes and obesity, one with Helsinn Healthcare in chemotherapy induced diarrhea and a license agreement with AbbVie in acute kidney injury.

For further information: www.zealandpharma.com

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