

Press Release  
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## Zealand informs that Sanofi has confirmed development plans for LixiLan at Investor Relations Thematic Seminar

- Phase III studies of LixiLan on track with completion expected by Q3 2015
- LixiLan presented as a potential first injectable medicine for Type 2 diabetes patients insufficiently controlled on OADs, and as potential basal intensification for patients uncontrolled with basal therapy

*Copenhagen, 21 November 2014* – Zealand Pharma A/S (“Zealand”) (Nasdaq Copenhagen: ZEAL) informs that Sanofi has confirmed that the Phase III development of LixiLan remains on track with expected completion by Q3 2015. LixiLan is an investigational fixed-ratio combination of insulin glargine (Lantus®), the leading basal insulin, with lixisenatide (Lyxumia®), a GLP-1 receptor agonist invented by Zealand, in a single daily injection for the treatment of adults with type 2 diabetes. Sanofi gave the update at its Investor Relations Thematic Seminar on New Medicines, held yesterday at 8:30am – 1:00pm ET / 2:30pm – 7:00 pm CET in New York, U.S.

Sanofi also stated that results from the ELIXA CV Outcome study of lixisenatide are expected in Q2 2015 and that the company plans for an FDA submission of LixiLan as early as at the end of 2015.

LixiLan was presented by Sanofi as a late-stage pipeline asset to be considered amongst the company’s next wave of innovative investigational new medicines. The LixiLan Phase III program includes two studies:

- LixiLan-O (1,125 patients) evaluating LixiLan as a potential first injectable medicine for patients with Type 2 diabetes insufficiently controlled on oral anti-diabetes drugs (OADs), and
- LixiLan-L (700 patients) evaluating LixiLan as potential basal intensification for patients with Type 2 diabetes uncontrolled with basal therapy.

Sanofi also provided a summary of results from the Phase IIb proof-of-concept study in 323 patients with Type 2 diabetes, presented on at ADA and at EASD earlier in 2014. Results from the study show that LixiLan gave a robust reduction in HbA1c (three months blood sugar level) from 8.1% to 6.3% with 84% of the patients on LixiLan having achieved the HbA1c target of <7%. Patients treated with LixiLan also had a reduction in body weight (-1kg) and experienced less frequent nausea and vomiting compared to what has been reported for the GLP-1 class and a low incidence rate of symptomatic hypoglycemia.



**David H. Solomon, President and Chief Executive Officer of Zealand**, commented: *"We are pleased to see Sanofi presenting LixiLan as a key asset in the company's portfolio of late stage investigational new medicines. The Phase III studies of LixiLan are on track with a prospective regulatory filing now confirmed for as early as end next year, which would represent a key milestone for Zealand's pipeline of partnered medicines. As the design of the two phase III studies indicates, LixiLan has the potential to offer benefits to a large group of diabetes patients."*

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**About Zealand Pharma**

Zealand Pharma A/S ("Zealand") (Nasdaq 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 possesses in-house competences also in clinical trial design and management with a therapeutic focus on metabolic diseases and acute care indications. The company is advancing a proprietary pipeline of novel medicines alongside a partnered product and development portfolio.

Zealand's first invented medicine, lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, is marketed globally (ex-US) as Lyxumia® and in Phase III development as a single-injection combination with Lantus® (LixiLan), both under a global license agreement with Sanofi. US regulatory filing of Lyxumia® is planned for summer 2015 and of LixiLan as early as end 2015.

Zealand's proprietary pipeline includes danegaptide (prevention of ischemic reperfusion injury) and the stable glucagon product, ZP4207 (treatment of severe hypoglycemia) as well as several preclinical peptide therapeutics. Partnering represents an important component of strategy to leverage in-house expertise, share development risk in large clinical trials, provide funding and commercialize the company's products. Zealand currently has global license agreements and partnerships with Sanofi, Helsinn Healthcare, Boehringer Ingelheim and Eli Lilly.

For further information: [www.zealandpharma.com](http://www.zealandpharma.com) Follow us on Twitter @ZealandPharma