Company announcement – No. 1 / 2016

Zealand clarifies its role in US patent litigation relating to lixisenatide and confirms its confidence in a strong patent status for the product

Copenhagen, 4 February 2016 – In response to market speculation about patent litigation in the US relating to lixisenatide, Zealand informs that it is not a party to the US proceedings. Zealand is aware of the patent litigation and other invalidity proceedings before the US Patent and Trademark Office, which are pending between Sanofi and AstraZeneca, and is keeping informed of their status and monitoring developments closely.

With regard to the potential consequences for Zealand of this ongoing litigation, the company confirms its confidence that the practice by Sanofi of the rights licensed to it by Zealand does not infringe AstraZeneca patents that are valid and enforceable. In light of the strong intellectual property position of lixisenatide in the US and elsewhere, Zealand does not expect that the pending proceedings will affect the company or its outlook.

Lixisenatide is a once-daily prandial GLP-1 analogue for the treatment of Type 2 diabetes, invented at Zealand, and with global development and commercialization rights licensed to Sanofi. Lixisenatide is marketed as Lyxumia® in 50 countries and was filed by Sanofi for regulatory approval in the US in late July 2015. Sanofi has also developed a fixed-ratio combination of lixisenatide and insulin glargine (Lantus®), referred to by Zealand as "LixiLan", for the treatment of type 2 diabetes and which product was submitted for US regulatory approval in December 2015.

In a comment to the litigation relating to lixisenatide in the US, Britt Meelby Jensen, President and Chief Executive Officer of Zealand, stated: "*Pre-launch patent litigation is common for products which, like lixisenatide, have significant market potential. In December 2015, Sanofi submitted the lixisenatide and insulin glargine fixed ratio combination product (LixiLan), for regulatory review by the US FDA, including use of a Priority Review Voucher in the process. The submission and use of the Priority Review Voucher, which was acquired by Sanofi for USD 245 million in order to reduce the expected FDA review period by four months, is to me a clear sign of Sanofi's strong belief in the combination product including lixisenatide, despite the ongoing litigation. Sanofi guides that US regulatory decisions on lixisenatide and on the lixisenatide/Lantus® combination are expected in Q3 2016, and at Zealand we remain confident in the strong intellectual property position of lixisenatide and are excited about its potential in both monotherapy and combination products.*"

Sanofi controls the litigation with AstraZeneca and Zealand will duly inform the markets in case of any new information from Sanofi or regarding the patent proceedings which might change the outlook for lixisenatide.

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About Zealand Pharma

Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) ("Zealand") is a biotech company with leading-edge scientific expertise in turning peptides into medicines. Zealand has a growing proprietary pipeline of novel specialty drug candidates and a mature portfolio of products and projects under license collaborations with Sanofi, Helsinn Healthcare and Boehringer Ingelheim.

Zealand's first invented medicine, lixisenatide, a once-daily prandial GLP-1 analogue for the treatment of Type 2 diabetes, is marketed globally (ex-US) as Lyxumia® by Sanofi and under regulatory review in the US. The license agreement with Sanofi covers a single-product combination of lixisenatide and insulin glargine (Lantus®), which is referred to as LixiLan. The combination product has been submitted for regulatory priority review in the US and regulatory submission is expected in the EU in Q1 2016.

The proprietary pipeline includes; *danegaptide* for ischemic reperfusion Injuries (Phase 2); *ZP1848* for Short Bowel Syndrome (Phase 2); and the *stable glucagon analogue, ZP4207* for single-dose use in a rescue pen for severe hypoglycemia (Phase 2) and for multiple-dose use to improve glucose control in diabetes (Phase 1); *ZP2929* for diabetes/obesity (Phase 1); and several preclinical peptide therapeutics.

The company is based in Copenhagen (Glostrup), Denmark. For further information about Zealand's business and activities, please visit: www.zealandpharma.com or follow us on Twitter @ZealandPharma