Zealand initiates Phase IIa clinical trial with dasiglucagon in a dual-hormone artificial pancreas system from Beta Bionics

- An automated delivery system with both insulin and glucagon holds potential to become a paradigm shift in the treatment of type 1 diabetes
- In December, Zealand initiated two Phase IIa trials, to test dasiglucagon’s potential in a dual-hormone artificial pancreas system
- Results from both trials are expected in H1 2017

**Copenhagen, 13 December 2016** – Zealand Pharma (Zealand) today announced that it has dosed the first patients in its Phase IIa clinical trial with dasiglucagon in a dual-hormone artificial (or bionic) pancreas system from Beta Bionics. Dasiglucagon is a Zealand-invented glucagon analogue with a unique stability profile in liquid formulation. The multiple-dose version of dasiglucagon is intended for use in a dual-hormone artificial pancreas system to better control hypoglycaemia and, potentially, hereby provide insulin treated diabetes patients with options for easier and more effective management of their disease.

The Phase IIa trial is the fourth Phase II trial initiated by Zealand this year, demonstrating the significant progress in Zealand’s pipeline of proprietary product candidates.

People with type 1 diabetes depends on a complex daily insulin regimen to control their blood glucose. They must regularly track and adjust their blood sugar levels to reduce the acute and chronic risks associated with hypo- and hyperglycaemia. A dual-hormone artificial (or bionic) pancreas system, which automatically delivers insulin and glucagon, aims to mimic the function of a healthy pancreas.

**Steven J. Russell, MD, Massachusetts General Hospital Diabetes Center in Boston, MA, USA, and Principal Investigator:**

“Our previous studies have shown that a dual-hormonal bionic pancreas can provide very effective management of glycemia in people with type 1 diabetes. All of our previous studies have used glucagon that have very limited stability, so the glucagon pump had to be refilled daily. More importantly, the unstable glucagon formulations will not meet the regulatory requirements to be approved for use in a bionic pancreas. This Phase IIa study will test the effectiveness of the stable glucagon analogue dasiglucagon in the dual-hormone bionic pancreas, comparing it with the unstable glucagon formulation that we have used in all of our previous studies. Demonstrating the effectiveness of a stable glucagon formulation or analogue, such as dasiglucagon, is an essential step towards making a dual-hormone bionic pancreas available to patients.”

**Adam Steensberg, Senior Vice President, Chief Medical & Development Officer, Zealand:**

“We are happy to have initiated our fourth Phase II trial this year, showing significant progress in our clinical pipeline of medicines that we fully own and develop ourselves. This is the first trial evaluating Zealand’s glucagon analogue, dasiglucagon, in the clinic for use in the dual-hormone artificial pancreas,

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1 Dasiglucagon is a proposed International Nonproprietary Name (pINN)
Zealand entered into a collaboration with Beta Bionics, a Boston-based company, earlier this year. Beta Bionics is developing a dual-hormone artificial (bionic) pancreas system based on advanced technology that was conceived and refined at Boston University and has been undergoing clinical trials for nearly 10 years at the Massachusetts General Hospital and, more recently, Stanford University, the University of North Carolina and the University of Massachusetts. The technology is being integrated at Beta Bionics into a pocket-sized wearable medical device called the iLet™.

The Phase IIa trials
The aim of the Phase IIa clinical trial with Beta Bionics is to assess, for the first time, the safety, efficacy and tolerability of dasiglucagon as part of the Beta Bionics dual-hormone artificial (bionic) pancreas system in adult patients with type 1 diabetes, compared to a recombinant market glucagon. In collaboration with Beta Bionics and Boston University, the trial is conducted at the Massachusetts General Hospital Diabetes Research Center in Boston, MA, USA, with MD Steven J. Russell as Principal Investigator.

Earlier this month, Zealand initiated another Phase IIa trial with the aim of assessing PK and PD responses after administration of the multiple-dose version of dasiglucagon in adult patients with type 1 diabetes. The first patients have been dosed.

The Phase IIa trials are designed to provide the foundation for longer clinical trials with the multiple-dose version of dasiglucagon in the dual-hormone artificial pancreas system. Results from both trials are expected in H1 2017.

For further information on the Phase IIa trials, see:
ClinicalTrials.gov Identifier: NCT02916251
ClinicalTrials.gov Identifier: NCT02971228

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About Zealand Pharma A/S
Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) (“Zealand”) is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a portfolio of medicines and product candidates under licence collaborations with Sanofi, Boehringer Ingelheim and Helsinn, and a pipeline of proprietary product candidates that primarily target specialty diseases with significant unmet needs.
The company’s first invented medicine, lixisenatide, a once-daily prandial GLP-1 analogue for the treatment of type 2 diabetes, is licensed to Sanofi. Lixisenatide is marketed as Lyxumia® outside the United States and approved as Adlyxin™ in the United States. Lixisenatide has been developed in a fixed-ratio combination with basal insulin glargine (Lantus®) and is approved as Soliqua™ 100/33 in the United States, and in Europe a CHMP positive opinion recommendation was given in November (Suliqua™ is the brand name in Europe).

Zealand’s proprietary pipeline includes: dasiglucagon* (ZP4207) (single-dose rescue treatment) for acute, severe hypoglycaemia (phase II); glepaglutide* (ZP1848) for short bowel syndrome (phase II); dasiglucagon* (ZP4207) (multiple-dose version) intended for use in a dual-hormone artificial pancreas system for better hypoglycaemia control and diabetes management (in phase II); and other earlier-stage clinical and preclinical peptide therapeutics.

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

* Dasiglucagon and glepaglutide are proposed International Nonproprietary Names (pINN).