Zealand Pharma reports completion of the second and pivotal Phase 3 trial with dasiglucagon for the treatment of severe hypoglycemia

- Last patient visit concluded in the multinational pivotal Phase 3 trial ahead of previous guidance, with key results now expected in Q3 2018,
- Dasiglucagon is a potential first-in-class soluble glucagon analog in a ready-to-use rescue pen, the HypoPal®, to treat severe hypoglycemia
- The first Phase 3 trial with dasiglucagon for treatment of severe hypoglycemia was reported to have successfully met its primary objective in Q1 2018

Copenhagen, Denmark, May 28, 2018 – Zealand Pharma announces that all subjects have been enrolled and dosed in the second and pivotal Phase 3 trial to confirm the clinical efficacy and safety of dasiglucagon for the rescue treatment of severe hypoglycemia in patients with type 1 diabetes.

Dasiglucagon is a potential first-in-class, soluble glucagon analog invented and developed by Zealand Pharma. It has a unique stability profile in liquid formulation and is suitable for a ready-to-use rescue pen, the HypoPal®, to treat severe hypoglycemia. Phase 2 clinical results showed that dasiglucagon rapidly increased plasma glucose levels after insulin-induced hypoglycemia, with a longer-lasting and more pronounced plasma glucose increase, compared to the active comparator.

The primary aim of this second and pivotal Phase 3 trial is to confirm a rapid increase in plasma glucose after single dose administration of dasiglucagon (0.6mg) to type 1 diabetes mellitus subjects with insulin-induced hypoglycemia, as compared to placebo. The trial was conducted in 156 Type 1 Diabetes patients, exposed to either dasiglucagon, placebo or reconstituted glucagon in a parallel randomized double-blind design (ClinicalTrials.gov identifier: NCT03378635). Results from the trial are now expected already in Q3 2018.

The first Phase 3 trial with dasiglucagon for treatment of severe hypoglycemia was reported to have successfully met its primary objective in March 2018. The primary aim of that trial was to evaluate the immunogenicity of repeated single doses of dasiglucagon (0.6 mg) following subcutaneous administration in 90 patients with type 1 diabetes. Further topline results from that trial are expected during Q2 2018.

Adam Steensberg, Executive Vice President, Chief Development and Medical Officer of Zealand, comments: “We are excited to be ahead of schedule in completing this pivotal Phase 3 trial and we look forward to the results in Q3, bringing us one step closer to making our HypoPal® rescue pen available to patients. Most insulin-dependent people with diabetes and their relatives live in constant fear of experiencing too low blood sugar. A user-friendly solution to address severe hypoglycemia holds great potential to significantly reduce this fear and to ensure better patient care.”

Dasiglucagon (glucagon analog stable in liquid formulation)
The Company is also pursuing two other indications where dasiglucagon’s stable profile in a liquid formulation would provide new treatment options:

- **Dasiglucagon for congenital hyperinsulism**
  Zealand is developing dasiglucagon as a potential treatment option for CHI, a rare disease affecting mainly newborns and toddlers. It is caused by a defect in the pancreatic beta cells, resulting in insulin overproduction. The FDA’s approval of Zealand’s IND application allows the Company to proceed into Phase 3 development of dasiglucagon for the treatment of CHI.
Dasiglucagon dual hormone pump therapy for diabetes

A next-generation artificial pancreas device containing both insulin and glucagon (dasiglucagon) which, guided by an algorithm, could maintain and control blood glucose levels without the need for patient intervention. A Phase 2b study is planned to start later this year to test dasiglucagon in a home-use setting in the iLet™, a bionic pancreas system developed by Beta Bionics.

Type 1 diabetes and hypoglycemia

People with type 1 diabetes suffer from insulin deficiency and inappropriate glucagon secretion. Both hormones are essential to ensure stable and healthy blood glucose levels. Consequently, patients must monitor and adjust their blood glucose levels to remain in proper glycemic control, as both high and low blood glucose may affect their health, both in the short and long term.

Severe hypoglycemia is an acute, life-threatening condition resulting from a critical drop in blood glucose levels associated primarily with insulin therapy. Severe hypoglycemia is most frequently seen in people with type 1 diabetes due to injecting insulin multiple times daily. Severe hypoglycemic events occur when blood glucose levels become critically low and it is the biggest concern for insulin-dependent patients and the most feared complication of diabetes treatment. It is a condition characterized by confusion, seizures and, often, loss of consciousness which, if left untreated, can result in death. The patient requires assistance from another person to treat.

Currently marketed formulations of glucagon for the treatment of severe hypoglycemia require mixing first by the person assisting to treat and then immediate administration due to poor drug stability. Dasiglucagon is being developed to offer a stable ready-to-use rescue treatment, the HypoPal®, for severe hypoglycemia.

Reference

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About Zealand Pharma A/S
Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) (“Zealand”) is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a late-stage clinical portfolio of proprietary product candidates focusing on specialty gastrointestinal and metabolic diseases. In addition, it has two marketed products, commercialized by Sanofi, and two product candidates under license collaboration with Boehringer Ingelheim.

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 LinkedIn or Twitter @ZealandPharma.