Company announcement – No. 35 / 2019

Zealand Pharma achieves primary and all key secondary endpoints in pediatric Phase 3 trial with dasiglucagon for severe hypoglycemia

- **Median time to recovery from low blood glucose in pediatric patients was 10 minutes following dasiglucagon injection, confirming the fast recovery also seen in adult patients with diabetes**
- **The study results support the use of same dose of dasiglucagon in adults and children**
- **The dasiglucagon HypoPal® rescue pen is being developed as an easy-to-use, fast and effective rescue treatment for diabetes patients having a severe hypoglycemic event**
- **On-track for submission of New Drug Application to U.S. FDA in early 2020**

Copenhagen, September 24, 2019 – Zealand Pharma A/S ("Zealand") (Nasdaq: ZEAL), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces positive results in the pediatric Phase 3 trial with dasiglucagon for severe hypoglycemia in diabetes. Dasiglucagon is a potential first-in-class soluble glucagon analog invented and developed by Zealand. It is being developed in the ready-to-use HypoPal® rescue pen: an auto-injector for easy, fast and effective treatment of severe hypoglycemia in people with diabetes.

The trial compared the glycemic response observed after induction of hypoglycemia and administration of dasiglucagon (0.6 mg) with that of placebo and that of GlucaGen® (1 mg), a currently marketed glucagon in powder form for reconstitution prior to injection. The primary endpoint was time to plasma glucose recovery, which was defined as first increase in plasma glucose of >/=20 mg/dL (1.1 mmol/L) from baseline without administration of rescue intravenous glucose. 42 pediatric subjects (divided into age groups of 6-11 and 12-17 years) were included in the trial: 21 in the dasiglucagon arm, 11 in the placebo arm, and 10 in the GlucaGen® arm. Additional details about the trial are found at https://clinicaltrials.gov/show/NCT03667053.

The primary result demonstrated that the median time to blood glucose recovery was 10 minutes for dasiglucagon, which was superior to placebo (median: 30 min; $p<0.001$). The median time to recovery for GlucaGen® was 10 minutes.

Overall, no safety concerns were raised for dasiglucagon within the trial. Nausea and vomiting were reported with dasiglucagon in both age groups (6-11 years; nausea: 25% and vomiting: 25%; 12-17 years; nausea: 92% and vomiting: 67%). For GlucaGen® (6-11 years; nausea: 50% and vomiting: 25%; 12-17 years; nausea: 17% and vomiting: 0%).

Adam Steensberg, Executive Vice President and Chief Medical and Development Officer at Zealand Pharma, commented: "I am thrilled with yet another positive Phase 3 trial outcome for our dasiglucagon HypoPal® rescue pen program. This study in children with diabetes confirms the potential for fast and effective rescue from severe hypoglycemia also seen in our Phase 3 trials in adults, and keeps us on track for submitting the new drug application to the U.S. FDA in early 2020."

This is the fourth consecutive Phase 3 trial with positive results for dasiglucagon. The previous immunogenicity and pivotal Phase 3 trials established dasiglucagon's safety profile and fast onset of action when administered via both the HypoPal® rescue pen and the pre-filled syringe in adult patients with type 1 diabetes.

"I believe that the dasiglucagon HypoPal® rescue pen and its innovative features have the potential to significantly improve management of severe hypoglycemia in diabetes," said **Emmanuel Dulac, President and Chief Executive Officer at Zealand Pharma**. "Dasiglucagon has repeatedly demonstrated fast recovery from hypoglycemia, typically within 10 minutes from injection. Speed of recovery is critical in any rescue situation, and our vision is for every patient at risk of severe hypoglycemia to have the HypoPal® rescue pen readily available."

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Dasiglucagon (glucagon analog stable in liquid formulation) for use in other indications
Dasiglucagon is a Zealand Pharma-invented glucagon analog with a unique stability profile in a ready-to-use aqueous solution. It is also in development for two additional indications: treatment of type 1 diabetes with a next-generation artificial pancreas, and treatment for children born with a genetic mutation that causes congenital hyperinsulinism (CHI).

About 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 occurs most frequently in people with type 1 diabetes due to injecting insulin multiple times daily. It is the biggest concern for insulin-dependent patients and the most feared complication of diabetes treatment. The condition is characterized by confusion, seizures, and often loss of consciousness that can result in death if left untreated.

When a patient has a hypoglycemic event, a second person must assist in treatment. 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 for severe hypoglycemia.

About Zealand Pharma A/S
Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) ("Zealand") is a biotechnology company focused on the discovery and development of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's current pipeline of internal product candidates focus on specialty gastrointestinal and metabolic diseases. Zealand's portfolio also includes two clinical license collaborations with Boehringer Ingelheim and pre-clinical license collaboration with Alexion Pharmaceuticals.

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