

Company announcement – No. 24 / 2018

Zealand Pharma has initiated the Phase 3 trial with dasiglucagon for treatment of severe hypoglycemia in children

- The pediatric Phase 3 trial will enroll up to 40 children with Type 1 diabetes and evaluate time to recovery from insulin-induced low blood glucose
- In the pivotal Phase 3 trial, 99% of the adult Type 1 diabetes patients recovered from low blood glucose within 15 minutes following dasiglucagon injection

Copenhagen, September 27, 2018 – Zealand Pharma A/S (“Zealand”) (Nasdaq: ZEAL), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, today announced initiation of the Phase 3 trial with dasiglucagon for treatment of severe hypoglycemia in children.

Dasiglucagon is a potential first-in-class soluble glucagon analog invented and developed by Zealand. It is in development in the ready-to-use HypoPal[®] rescue pen for easy, fast and effective treatment of severe hypoglycemia.

This Phase 3 trial focuses on treating children with type 1 diabetes with a single dose of dasiglucagon to rapidly increase blood glucose levels following insulin-induced hypoglycemia. It is a randomized, double-blind, placebo- and active-controlled, parallel-arm trial to assess the efficacy, safety, and pharmacokinetics of dasiglucagon relative to placebo and GlucaGen[®] when administered as a rescue therapy for severe hypoglycemia in children with T1DM treated with insulin. The trial compares the glycemic response observed after administration of dasiglucagon to that of currently marketed glucagon, in powder form for reconstitution prior to injection. The primary endpoint is time to plasma glucose recovery, which is defined as first increase in plasma glucose of ≥ 20 mg/dL (1.1 mmol/L) from baseline without administration of rescue intravenous glucose. More trial details are available at <https://clinicaltrials.gov/ct2/show/NCT03667053>.

“Our pivotal Phase 3 results in adults with type 1 diabetes suggest that the dasiglucagon HypoPal[®] rescue pen could become a fast and effective treatment for severe hypoglycemia. We now broaden the scope by studying dasiglucagon in children with type 1 diabetes, as severe hypoglycemia is of particular concern for this age group and their families,” said **Adam Steensberg, Executive Vice President and Chief Medical & Development Officer at Zealand**.

This pediatric trial follows Zealand’s September 18, 2018 announcement of positive results from a pivotal Phase 3 trial using dasiglucagon to treat severe hypoglycemia in adults with type 1 diabetes. The primary result demonstrates that the median time to blood glucose recovery was 10 min for dasiglucagon, which was superior to placebo (median: 40 min; $p < 0.001$). The median time to recovery for GlucaGen[®] was 12 min. 99% of subjects were recovered from the insulin-induced hypoglycemia within 15 min following dosing with dasiglucagon, versus 2% with placebo and 95% with GlucaGen[®].



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About dasiglucagon (glucagon analog stable in liquid formulation) for use in other indications

Dasiglucagon is a Zealand-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.

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.