

Zealand Pharma presents clinical and non-clinical evidence for dasiglucagon rescue therapy at the 80th Scientific Sessions of the American Diabetes Association

- The dasiglucagon HypoPal® rescue pen is under FDA review as a potential fast and effective treatment of severe hypoglycemia in diabetes
- In Phase 3 trials in pediatric and adult patients with diabetes, dasiglucagon has consistently demonstrated a median time to recovery from hypoglycemia of 10 minutes

Copenhagen, June 14, 2020 – Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078), a biotechnology company changing lives with innovative peptide-based medicines, presented elaborated results from two Phase 3 clinical studies with dasiglucagon as treatment for severe hypoglycemia as well as one preclinical PK/PD study investigating aqueous versus DMSO formulations of glucagon and the pharmacodynamics of dasiglucagon in aqueous solution at the 80th Scientific Sessions of the American Diabetes Association (ADA) held as a virtual meeting June 12-16, 2020.

Dasiglucagon, a potential first-in-class soluble glucagon analog invented and developed by Zealand Pharma, has the potential to offer millions of people living with diabetes fast and effective treatment for severe hypoglycemia. It has been developed in the ready-to-use HypoPal® rescue pen for easy, fast and effective treatment. The New Drug Application for the treatment of severe hypoglycemia with dasiglucagon has been accepted for review by the U.S. Food and Drug Administration and given a PDUFA target action date of March 27, 2021 (Company Announcement No. 28 / 2020).

In an oral presentation, Professor Tadej Battelino, Professor of Pediatrics, University Children's Hospital Ljubljana presented **Dasiglucagon as a Fast and Effective Treatment for Severe Hypoglycemia in Children with Diabetes** (Abstract number: 180-OR). This Phase 3, three-arm, parallel trial in 42 children in the age range of 6-17 years old with Type 1 diabetes, investigated the recovery from insulin-induced hypoglycemia with dasiglucagon versus placebo and with Glucagen® as a reference. Primary and all secondary endpoints were met and demonstrated a median time to plasma glucose recovery of 10 minutes with dasiglucagon and 30 minutes for placebo ($p < 0.001$) and 10 minutes for Glucagen®. Dasiglucagon showed adverse events consistent with known class effects. No serious or severe adverse events were reported.

Dr. Timothy Bailey, President and CEO of AMCR Institute, presented a poster entitled **Dasiglucagon HypoPal® Autoinjector as a Fast and Effective Treatment for Severe Hypoglycemia: Results of a Phase 3 Trial** (Abstract Number: 1053-P). This Phase 3 parallel, two-arm study in 45 adults with Type 1 diabetes, investigated the recovery from insulin-induced hypoglycemia with dasiglucagon versus placebo. All primary and secondary endpoints were met and the median time to plasma glucose recovery was 10 minutes with dasiglucagon versus placebo 35 minutes, ($p < 0.0001$). Dasiglucagon was generally safe and well-tolerated and these results were consistent with prior pivotal Phase 3 trials evaluating dasiglucagon administered via a pre-filled syringe.



Dr. Carola Wenander, Principal Scientist, In Vivo Pharmacology at Zealand Pharma, presented a poster entitled ***PK/PD of Glucagon and the Novel Glucagon Analog, Dasiglucagon, in Aqueous or Non-Aqueous formulations following SC Administrations in Rats*** (Abstract Number: 1091-P). This PK/PD study in male Sprague-Dawley rats characterized the pharmacokinetics of glucagon in aqueous formulation (phosphate buffered solution) and that formulated in DMSO, and compared these to the pharmacodynamics of dasiglucagon in an aqueous formulation. The pharmacodynamic results of this preclinical model demonstrated that there was comparable blood glucose increase with glucagon and dasiglucagon in aqueous formulations. Glucagon in DMSO showed a delayed increase in blood glucose.

Adam Steensberg, Executive Vice President of Research and Development, and Chief Medical Officer at Zealand Pharma stated, “Zealand Pharma is focused on bringing life changing therapies to people with diabetes and believe that the data presented at ADA further demonstrate the potential of dasiglucagon as a fast and effective treatment for severe hypoglycemia in both adults and pediatrics.”

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Dasiglucagon (glucagon analog stable in liquid formulation) for use in multiple 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 four indications: treatment of severe hypoglycemia, treatment of type 1 diabetes with a next-generation artificial pancreas, treatment for children born with a genetic mutation that causes congenital hyperinsulinism (CHI), and mini doses to treat post prandial hypoglycemia.

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

Zealand Pharma (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development, and commercialization of next generation peptide-based medicines that change the lives of people living with metabolic and gastrointestinal diseases. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's robust pipeline of investigational medicines includes three candidates in late stage development, and one candidate being reviewed for regulatory approval in the United States. Zealand markets V-Go®, an all-in-one basal-bolus insulin delivery option for people with diabetes. License collaborations with Boehringer



Ingelheim and Alexion Pharmaceuticals create opportunity for more patients to potentially benefit from Zealand-invented peptide therapeutics.

Zealand was founded in 1998 in Copenhagen, Denmark, and has presence throughout the U.S. that includes key locations in New York, Boston, and Marlborough (MA). For more information about Zealand's business and activities, please visit <http://www.zealandpharma.com>.

Forward-Looking Statement

The above information contains forward-looking statements that provide Zealand Pharma's expectations or forecasts of future events. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forward-looking statements to be incorrect. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. All such forward-looking statements speak only as of the date of this press release and are based on information available to Zealand Pharma as of the date of this release.

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