

Company announcement – No. 62 / 2020

Zealand Pharma announces data from the first phase 3-trial with dasiglucagon in Congenital Hyperinsulinism (CHI)

- **Dasiglucagon on top of standard of care (SOC) did not significantly reduce the rate of hypoglycemia compared to SOC alone when assessed by intermittent self-measured plasma glucose (primary endpoint)**
- **However, hypoglycemia was reduced by 40–50% with dasiglucagon as compared to SOC alone when assessed by blinded continuous glucose monitoring (exploratory analysis)**
- **Dasiglucagon treatment was assessed to be safe and well tolerated in the study and 31 out of 32 patients continued into the long-term extension study**
- **Zealand Pharma will engage with regulatory authorities to discuss the results while awaiting the outcome of the second phase 3-trial in younger children with CHI**

Copenhagen, December 15, 2020 – Zealand Pharma A/S (NASDAQ: ZEAL) (CVR-no. 20 04 50 78), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces topline results from its first phase 3-trial with dasiglucagon as a treatment for the rare pediatric diseases, Congenital Hyperinsulinism (CHI).

In this study of 32 children with CHI (ages 3 months to 12 years), dasiglucagon treatment did not significantly reduce the number of intermittent self-measured plasma glucose (SMPG)-measured hypoglycemia events per week when compared to SOC alone. After one week of treatment stabilization, there was a similar decline in hypoglycemia events with both dasiglucagon and SOC treatment over the 3 weeks of comparison (primary endpoint). Continued improvement in hypoglycemia rates were observed during the subsequent 4 weeks of study when all participants were treated with dasiglucagon in addition to SOC. The mean rate of hypoglycemia declined from approximately 9 events/week at baseline to 3 events/week at end of trial (Week 8) in both treatment groups. For these assessments, including the primary endpoint in this study, a hypoglycemia event was defined as any plasma glucose <70 mg/dL or 3.9 mmol/L, as measured by intermittent SMPG.

However, dasiglucagon treatment resulted in 40-50% reductions in all measures of hypoglycemia assessed by blinded continuous glucose monitoring (CGM) (including number of events and time in hypoglycemia) compared to SOC treatment alone (all post-hoc $p < 0.05$). These findings were seen both for hypoglycemia defined as glucose <70 mg/dL and glucose <54 mg/dL.

Treatment with dasiglucagon was associated with higher rates of gastrointestinal symptoms and skin changes. Overall, dasiglucagon was assessed to be safe and well tolerated in the study.

A second phase 3 trial studying dasiglucagon treatment in younger children with CHI (enrolling 12 patients aged 7 days to one year) is ongoing. In addition, there is an ongoing safety extension trial for subjects with CHI completing the two randomized efficacy studies.

“We are disappointed this study did not meet the primary endpoint. However, we are encouraged by the meaningful reduction in hypoglycemic events observed with blinded CGM, and that all but one patient entered the long-term extension study,” stated Adam Steensberg, Chief Medical Officer at Zealand Pharma. “We remain committed to advancing dasiglucagon as a potential treatment of CHI due to the



significant unmet medical need for these children, and will work closely with regulatory authorities to define the path forward while awaiting the outcome of the second phase 3 trial in younger children with CHI.”

About the study (NCT 03777176)

The trial evaluated the potential of longer-term dasiglucagon infusion to limit the risk of hypoglycemia in children with CHI. The two-arm, open-label trial in 32 children with CHI (ages 3 months up to 12 years) compared dasiglucagon plus SOC versus SOC alone over 4 weeks. From week 5 until end of study (week 8) all participants were treated with dasiglucagon plus SOC. The trial was conducted at sites in the United States, Europe and Israel.

About CHI

CHI is a rare pediatric disease which affects mainly newborns, infants and toddlers. Due to a genetic defect in the insulin producing cells, these children have increased insulin levels, resulting in persistent and recurrent hypoglycemia throughout childhood. Current treatment options are limited, complex and may be insufficient to adequately control hypoglycemia.

About dasiglucagon

Invented by Zealand Pharma, dasiglucagon is a glucagon analog with a unique stability profile in a ready-to-use aqueous solution. The molecule has been designed to be stable in solutions and thus suitable for chronic pump use. In 2017, both the U.S. FDA and the European Commission granted orphan drug designation for dasiglucagon for the treatment of CHI.

Zealand is pursuing several indications where dasiglucagon’s stable profile could provide new treatment options: dasiglucagon HypoPal® rescue pen for severe hypoglycemia, dasiglucagon bi-hormonal artificial pancreas therapy for diabetes management and a mini-dose pen for treatment of hypoglycemia associated with other conditions.

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About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand Pharma have advanced into clinical development, of which two have reached the market. Zealand Pharma’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 Pharma 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 Pharma-invented peptide therapeutics.

Zealand Pharma 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 Pharma’s business and activities, please visit 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 release and are based on information available to Zealand Pharma as of the date of this release.

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