

Company Announcement - No. 28 / 2020

## Zealand Pharma announces FDA acceptance of New Drug Application for the dasiglucagon HypoPal® rescue pen for treatment of severe hypoglycemia

- The dasiglucagon HypoPal® rescue pen New Drug Application represents a major milestone in Zealand Pharma's efforts to bring life changing therapies to people with diabetes
- PDUFA target action date scheduled for March 27, 2021

Copenhagen, May 22, 2020 – Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL), a biotechnology company changing lives with innovative peptide-based medicines, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the company's New Drug Application (NDA) for the dasiglucagon HypoPal® Rescue Pen for the treatment of hypoglycemia in people with diabetes. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of March 27, 2021. Additionally, the FDA has communicated that it is not currently planning on an advisory committee to discuss the application.

"We are pleased by the FDA's acceptance of the NDA for the dasiglucagon HypoPal® rescue pen, several weeks ahead of the anticipated response date. It marks an important step toward bringing a potential treatment option to people with diabetes at risk of severe hypoglycemia," commented **Adam Steensberg, Executive Vice President, Research and Development, and Chief Medical Officer at Zealand Pharma.** "This represents yet another significant milestone achieved by the Zealand team. We look forward to continue working with the FDA during the review process towards potential approval in early 2021."

Zealand's ready-to-use dasiglucagon HypoPal rescue pen is designed to offer diabetes patients fast and effective treatment for severe hypoglycemia. In three Phase 3 trials in adults and pediatrics, the primary and all key secondary endpoints were successfully achieved with a median time to blood glucose recovery of only 10 minutes following injection of 0.6mg dasiglucagon. The Company remains on track for the potential launch of the dasiglucagon HypoPal rescue pen in early 2021.

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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 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-inone basal-bolus insulin delivery option for people with diabetes. License collaborations with Boehringer

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<sup>&</sup>lt;sup>1</sup> Company announcement nos. 23/2018, 15/2019 and 35/2019



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 <a href="https://www.zealandpharma.com">www.zealandpharma.com</a>.

## **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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