

## Zealand Pharma submits New Drug Application to the U.S. Food and Drug Administration for the Dasiglucagon HypoPal<sup>®</sup> Rescue Pen for treatment of severe hypoglycemia

- The Dasiglucagon HypoPal<sup>®</sup> Rescue Pen New Drug Application represents a major milestone in Zealand Pharma's efforts to bring life changing therapies to people with diabetes
- The submission encompasses three Phase 3 trials which met all primary and key secondary endpoints with a median time to recovery from hypoglycemia of only 10 minutes
- Zealand Pharma remains on-track to build commercial infrastructure in the U.S. for the anticipated Dasiglucagon HypoPal<sup>®</sup> Rescue Pen launch in 2021

*Copenhagen, March 31, 2020* – Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL), a Copenhagenbased biotechnology company focused on the discovery and development of innovative peptide-based medicines, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of the Dasiglucagon HypoPal<sup>®</sup> Rescue Pen for the treatment of hypoglycemia in people with diabetes.

"This is the first of four potential New Drug Applications over the next three years, and is a major milestone for Zealand Pharma," commented **Emmanuel Dulac, President and Chief Executive Officer at Zealand Pharma**. "We have a strong commitment toward bringing life changing therapies to patients and believe that the Dasiglucagon HypoPal Rescue Pen addresses a significant and underserved need among people living with diabetes."

"I am particularly proud that the team was able to deliver on our commitment to filing the New Drug Application for dasiglucagon before the end of the first quarter 2020, despite having to work remotely and under the difficult conditions caused by the COVID-19 crisis," commented **Adam Steensberg, Executive Vice President, Research and Development, and Chief Medical Officer at Zealand Pharma.** 

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.<sup>1</sup> The FDA typically has a 60-day filing review period to determine whether the NDA is sufficiently complete and acceptable for filing.

## For further information, please contact:

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

## 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, and is Zealand's lead drug in development to improve the treatment of metabolic diseases. It is in development for three indications in addition to severe hypoglycemia in diabetes: 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 treatment and prevent of hypoglycemia in individuals who have undergone gastric bypass bariatric surgery.

## 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 clinical license collaboration 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 <u>www.zealandpharma.com</u> or follow Zealand on LinkedIn or Twitter @ZealandPharma.