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Zealand Pharma Completes Enrollment in Phase 3 Trial of Dasiglucagon in Children with Congenital Hyperinsulinism (CHI)

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- Top-line results expected in the second quarter of 2022
- Pending positive results, Zealand intends to file for marketing approval with the US Food and Drug Administration

Copenhagen, DK and Boston, MA, U.S. February 15, 2022 – Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078,) a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines, today announced completion of patient enrollment in the second Phase 3-trial, 17103, of dasiglucagon for the treatment of Congenital hyperinsulinism (CHI) in neonates up to 12 months old. This Phase 3 study is the last in the program which constitute the largest clinical development program ever conducted in CHI.

CHI is the most frequent cause of severe and persistent hypoglycemia. It starts as early as the neonatal period and profoundly affects those children and their families through infancy and teenage years. It is characterized by an excessive and uncontrolled insulin secretion triggering recurrent episodes of profound hypoglycemia which require constant surveillance and rapid and intensive interventions to prevent neurological sequelae.

“We are delighted to reach this significant milestone for dasiglucagon as we work diligently to provide a much-needed treatment option for the children faced with this rare, life-threatening disease,” said Adam Steensberg, Chief Medical Officer at Zealand Pharma. “We are extremely grateful to the patients, their caregivers and clinicians who made this trial possible and look forward to the results in the second quarter of 2022..”

The 17103 Phase 3 trial is a pivotal, double blind and placebo controlled randomized trial designed to investigate the potential for chronic dasiglucagon infusion delivered via a pump to prevent hypoglycemia in children with CHI. The primary objective of the trial is to reduce or eliminate the need for intensive hospital treatment, reduce the frequency of dangerous low blood glucose and need for constant feeding, and to potentially delay or eliminate the need for pancreatectomy.

The FDA and the European Commission both granted orphan drug designation to dasiglucagon for the treatment of CHI. The first Phase 3 trial in the program was reported in December 2020. That trial evaluated children aged 3 months to 12 years old with more than three hypoglycemic events per week despite previous near-total pancreatectomy and/or maximum medical therapy. Top line results from the second Phase 3 trial are expected in the second quarter of 2022 and if the trial is positive Zealand plans to file for marketing approval with the US Food and Drug Administration based on data from both Phase 3 trials and an ongoing long-term extension safety trial.

About CHI
CHI is a rare pediatric disease that 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 that is stable in aqueous solution and is thus suitable for chronic pump use. In 2017, both the U.S. Food and Drug Administration (FDA) and the European Commission granted orphan drug designation for dasiglucagon for the treatment of CHI. In 2021 Zealand initiated a collaborating with DEKA on utilizing their continuous infusion pump for the potential treatment of CHI with dasiglucagon. Under the terms of this agreement Zealand is responsible for distribution and commercialization of the drug-device combination.

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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 peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market and three candidates are in late-stage development. In addition, license collaborations with Boehringer Ingelheim and AstraZeneca create opportunities for more patients to potentially benefit from Zealand-invented peptide investigational agents currently in development.

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

Forward-Looking Statements
This announcement may contain forward-looking statements, including "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, that are based on the beliefs and assumptions and on information currently available to management of Zealand, including with respect to the company's anticipated revenue and expenses for 2021 and potential product approval by the FDA. All statements other than statements of historical fact contained in this announcement are forward-looking statements, including statements regarding the anticipated final terms of the Investment. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Zealand's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Zealand's Annual Report on Form 20-F for the year ended December 31, 2019 filed with the SEC on March 13, 2020 and subsequent reports that Zealand has filed or will file with the SEC. Forward-looking statements represent Zealand's beliefs and assumptions only as of the date of this announcement. Although Zealand believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, Zealand assumes no obligation to publicly update any forward-looking statements for any reason after the date of this announcement to conform any of the forward-looking statements to actual results or to changes in its expectations.

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