

Press release - No. 08 / 2020

# Zealand Pharma presents elaborated results on the use of regular human insulin delivered by V-Go<sup>®</sup> in older adults with type 2 diabetes, at the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association

- In older adults with type 2 diabetes, use of human regular insulin delivered by V-Go<sup>®</sup>
  demonstrated similar glycemic control with no increased hypoglycemia risk compared to
  use of rapid acting insulin analogs
- The use of U-100 Regular Human Insulin with V-Go® Wearable Insulin Delivery device has not yet been cleared by the Food and Drug Administration or European Union

Copenhagen, June 13, 2020 – Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078), a biotechnology company changing lives with innovative peptide-based medicines, presented during the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA) two elaborated results from a 14-week multi-center randomized, parallel trial comparing safety and clinical outcomes between the use of human regular insulin (HRI) compared to rapid acting insulin (RAI) when delivered by V-Go in adults with type 2 diabetes. For more information, visit <a href="https://www.clinicaltrials.gov/ct2/show/NCT01326598">https://www.clinicaltrials.gov/ct2/show/NCT01326598</a>. The scientific sessions were held as a virtual meeting June 12-16, 2020.

Dr. Pablo F Mora, Endocrinologist, Dallas Diabetes Research Center, Dallas, Texas presented a poster entitled *Comparison of Hypoglycemia Safety between U-100 Human Regular Insulin and Rapid Acting Insulin Delivered by V-Go Wearable Insulin Delivery in Type 2 Diabetes* (Abstract number: 1005-P). This analysis comprised an extensive review of the hypoglycemia safety data from the full study population (N=136) and suggests that in a Type 2 Diabetes population, the risk of hypoglycemia is not increased when using HRI compared to RAI in V-Go.

In a second poster presentation based on the same 14-week study, Dr. David R Sutton, Endocrinologist, Northeast Florida Endocrine and Diabetes Associates, Jacksonville, Florida, presented the *Efficacy and Safety Comparison between U-100 Human Regular Insulin and Rapid Acting Insulin when Delivered by V-Go Wearable Insulin Delivery in an Older Type 2 Diabetes Population*, (Abstract number: 987-P). This post-hoc exploratory analysis in fifty-three subjects evaluated the clinical and safety outcomes between the use of HRI and RAI delivered by V-Go in an adult population 65 years of age or older. Findings suggest non-inferiority for change in overall blood sugar (A1C) and similar hypoglycemia event rates between the groups when switching from RAI to HRI.

"Addressing the patient's ability to afford insulin therapy is important to the management of diabetes," commented **Adam Steensberg**, **Executive Vice President of Research and Development**, **and Chief Medical Officer** at Zealand Pharma. "We are pleased with the results of this study evaluating use of a more affordable human regular insulin with V-Go wearable insulin delivery device in older adults with type 2 diabetes, and hope to make this treatment solution available to benefit patients as soon as possible."

###

# **About the Study**

This study was managed and executed by East Coast Institute for Research (ECIR) with enrollment conducted across three study sites in the United States, Northeast Florida Endocrine and Diabetes

Zealand Pharma A/S 1/3



Associates in Jacksonville, Florida, by Principal Investigator David Sutton, MD, FACE, The Jones Center for Diabetes and Endocrine Wellness in Macon, Georgia by Principal Investigator Ashwini Gore, MD, and in Columbus, Georgia by Bantwal Baliga, MD.

# V-Go® Wearable Insulin Delivery Device

V-Go® has been cleared for use in adult patients requiring insulin by the Food and Drug Administration in the United States and has received CE Mark approval. The use of U-100 Regular Human Insulin with V-Go® Wearable Insulin Delivery device has not been cleared by the Food and Drug Administration or European Union. A U-100 fast acting insulin should be used with V-Go®. Insulin lispro, rDNA origin and insulin aspart, rDNA origin have been tested by the manufacturer and found to be safe for use in the V-Go® Wearable Insulin Delivery Device. V-Go was acquired by Zealand Pharma on April 2, 2020, and is now manufactured and commercialized as part of Zealand's portfolio of life changing therapeutics. Learn more at www.go-vgo.com.

### **About Zealand Pharma**

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

## **Forward-Looking Statement**

The above information contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These include statements with respect to Zealand's plans to publish data from its clinical trial and the potential therapeutic benefits and availability of the V-Go device, and, therefore, you are cautioned not to place undue reliance on them. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, including that Zealand has incurred net losses in recent periods and may continue to do so, Zealand depends on collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and market and sell its products and product candidates, Zealand may need to raise additional funding, which may not be available on acceptable terms or at all, Zealand may be unable to successfully integrate the V-GO device into its organization. Zealand expects its operating loss to increase in the near-term. Zealand's products may have major side effects that may give rise to substantial liability claims, and Zealand's financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. You should refer to the risk factor disclosure set forth in the documents Zealand files with the Danish Business Agency and with the Securities and Exchange Commission available at www.sec.gov, including without limitation in the section entitled "Risk Factors" in Zealand's Annual Report on Form 20-F for the fiscal year ended December 31, 2019 and subsequent reports and filings by the Company. These risks and uncertainties 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, Zealand's 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 as of the date of this release. Zealand disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

# For further information, please contact:

Zealand Pharma Investor Relations +45 50 60 38 00 investors@zealandpharma.com

**Lani Pollworth Morvan**, Investor Relations and Communication <a href="mailto:LMorvan@zealandpharma.com">LMorvan@zealandpharma.com</a>