

Company announcement – No. 20 / 2020

Zealand Pharma presents positive clinical and health economic outcome data with use of regular human insulin delivered by the V-Go in adults with type 2 diabetes

- **Results of this 14-week randomized multi-center trial demonstrate non-inferiority for change in overall blood sugar levels (HbA1c) between U-100 regular human insulin and U-100 rapid acting insulin analogs when delivered by V-Go®**
- **The 30-day insulin cost per patient was calculated to be \$265.16 for the regular human insulin group and \$533.70 for the rapid acting insulin group at the end of trial**
- **V-Go® is a patient fillable insulin delivery device cleared by the FDA for the administration of insulin for the management of diabetes mellitus in adults requiring insulin**
- **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, April 15, 2020 – Zealand Pharma A/S (“Zealand”) (NASDAQ: ZEAL) (CVR-no. 20045078), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces clinical non-inferiority and positive health economic outcomes with use of regular human insulin (RHI) versus rapid acting insulin (RAI) when delivered by V-Go®. Clinical outcomes of the trial are highlighted in a press release issued by Endocrine Society and the full abstract will be published in a supplemental issue of the Journal of the Endocrine Society. Health economic outcomes will be published online in April in the Journal of Managed Care & Specialty Pharmacy supplement.

This 14-week randomized, non-inferiority trial was conducted in a real-world practice setting under usual standard of care across three centers in the United States. Patients administering U-100 RAI analogs with V-Go® were randomly assigned to either continue RAI delivery by V-Go® or switch to U-100 RHI. The primary end-point was change in overall blood glucose levels (HbA1c), assessments of safety measures and insulin costs* were evaluated as secondary endpoints. For more information, visit <https://www.clinicaltrials.gov/ct2/show/NCT01326598>.

Results of the trial demonstrate non-inferiority for change in HbA1c between RHI and RAI (-0.60% for RHI vs -0.38% for RAI with an estimated treatment difference (ETD) of -0.22%; 95% confidence interval: -0.67% to 0.22%; non-inferiority margin <0.4% and p=0.007). From a baseline 30-day insulin cost of \$515.68 for patients switched to RHI and \$518.31 for patients continuing RAI, the 30-day change in insulin cost at study end was -\$250.50 for RHI and +\$15.35 for RAI (ETD: -\$265.85; p<0.0001). The mean change in total daily dose of insulin with RHI was 0.8 U/day from a baseline of 61.0 U/day vs 1.8 U/day from a baseline of 61.3 U/day with RAI (ETD: -1.04 U/day; p=0.34). No significant difference for patient-reported hypoglycemia were observed by the end of the study. No intervention-related moderate or severe adverse events were reported in either group. One mild event (upset stomach) possibly related to the intervention was reported in the RHI group and two mild events (skin irritation and skin welt) in the RAI group.

“With the rising cost of healthcare, patients and providers continue to look for effective and affordable ways to treat diabetes” commented **Adam Steensberg, Executive Vice President of Research and Development, and Chief Medical Officer** at Zealand Pharma. “These results show that V-Go may allow diabetes patients to achieve their treatment goals with more affordable regular human insulin. We hope to make this treatment solution available to benefit patients as soon as possible.”



“Delivery of a lower-cost regular human insulin by V-Go[®], when compared to analog insulin, resulted in similar efficacy for controlling blood sugar at a significant cost savings,” said **Pablo Mora, MD, FACE, CDCES, from the Dallas Diabetes Research Center, Coordinating Investigator** for the study. “Expanding the affordability of insulin therapies can have positive implications on insulin adherence and lead to improved clinical outcomes for patients struggling to afford insulin therapy.”

*Cost of insulin calculated at baseline and study end based on multiplying the prescribed total insulin units for a 30-day period by the published average wholesale acquisition insulin unit cost for rapid acting insulins (RAI) or regular human insulins (RHI) as applicable based on study time point. Insulin lispro, rDNA origin and insulin aspart, rDNA origin averaged for RAI unit cost and insulin human injection and regular human insulin, rDNA origin averaged for RHI unit cost. Wholesale acquisition cost based on ProspectoRx [database online]. <https://prospectorx.com>. Accessed December 2019.

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 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 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-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 www.zealandpharma.com.

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.

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