TANDEM INVESTOR CENTER

Data Presented at International Diabetes Conference Further Demonstrate Benefits of Tandem Diabetes Care Automated Insulin Delivery Technologies

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MADRID--(BUSINESS WIRE)--Feb. 20, 2020-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, announced positive data presented today on its automated insulin delivery technologies, including data from a study of the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed-loop technology demonstrating increased time in range (70 mg/dL -180 mg/dL)[1] in children ages six to thirteen. In a separate presentation, real-world data was presented on the t:slim X2 insulin pump with Basal-IQ® predictive low glucose technology, showing sustained reductions in sensor time spent below 70 mg/dL and improvements in user satisfaction compared to previous therapy. Data was presented during a corporate symposium at the 13th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD) in Madrid, Spain.

“These results align with our vision to establish Tandem as a global company that provides easy-to-use insulin therapy management solutions for improved clinical outcomes to children and adults living with diabetes,” said John Sheridan, president and chief executive officer. “In support of this goal, we plan to submit a regulatory filing with the FDA next month to expand the age indication for t:slim X2 with Control-IQ technology to include patients 6 years of age and older.”

Control-IQ Advanced Hybrid Closed Loop Technology Data

International Diabetes Closed Loop Protocol-5 (DCLP5) Study Results

Details from the Protocol 5 (DCLP5) of the National Institutes of Health (NIH)-funded International Diabetes Closed Loop (iDCL) program, an international consortium of academic centers led by the University of Virginia, were presented by Dr. R. Paul Wadwa, Associate Professor of Pediatrics, at the Barbara Davis Center for Diabetes, University of Colorado Anschutz Medical Campus, and the protocol chair for this trial.

“This study demonstrated that in school-aged children with type 1 diabetes, who often struggle with diabetes management for a variety of reasons, use of Control-IQ technology led to improved glucose control during both the day and night,” said Dr. Wadwa. “We are thrilled with these results and are hopeful that this system will ultimately offer a valuable treatment option to benefit children with type 1 diabetes.”

The DCLP5 study is a 16-week closed-loop study that included a dedicated control group, increasing the clinical significance of the study results. There were no exclusion criteria based on hemoglobin A1c (HbA1c), history of acute complications, or previous experience using an insulin pump or CGM. Following a two to eight-week run-in period, the length of which was determined based on previous pump and CGM experience, 101 patients with type 1 diabetes ages 6 to 13 were randomized 3:1 to Control-IQ technology (n=78) or sensor-augmented pump (SAP) therapy (n=23) and followed for 16 weeks. The entry HbA1c for participants in the study ranged from 5.7 to 10.1 with a mean of 7.9 in the SAP group and 7.6 in the Control-IQ technology group. Approximately 20 percent of participants were new to pump therapy and the large majority were already using a CGM. All participants completed the study.

Time in range (70 mg/dL – 180 mg/dL)[1] for children using Control-IQ technology for 6 months increased from 53 percent to 67 percent, compared to those in the control group who increased from 51 percent to 55 percent using SAP alone ($p<0.001$). During the overnight period, sensor time in range with Control-IQ technology was 80 percent compared to 54 percent in the control group.

Time spent with sensor glucose values above 180 mg/dL was 31 percent in those using Control-IQ technology compared to 43 percent in the control group ($p<0.001$). Sensor time spent below 70 mg/dL was very low at baseline (<2 percent in both treatment groups) and not different between groups at the 16-week follow up interval. These results were demonstrated in people with and without prior experience with insulin pump therapy. The treatment effect was evident in the first month and appeared consistent over 4 months. In addition to sensor time in range, those using Control-IQ technology also saw statistically significant reductions in mean sensor glucose.

No severe hypoglycemia or diabetic ketoacidosis (DKA) was reported in the study. The system operated in active closed-loop 93 percent of the 4-month time period.

International Diabetes Closed Loop Protocol-3 (DCLP3) Study Results

A review of the evolution of Control-IQ technology, and a summary of available Control-IQ clinical data was presented by Dr. Marc Breton, the Associate Director of Research for The Center for Diabetes Technology at the University of Virginia, and the Principal Investigator of the DCLP5 study. In addition, Dr. Breton presented details from the National Institutes of Health (NIH)-funded International Diabetes Closed Loop (iDCL) trial, Protocol 3 (DCLP3) in adults and adolescents.

The NIH-funded DCLP3 study was the first large-scale, 6-month closed-loop study that included a dedicated control group. There were no exclusion criteria based on hemoglobin A1c (HbA1c), history of acute complications, or previous experience using an insulin pump or CGM. Time in range (70 mg/dL – 180 mg/dL)[1] for participants using Control-IQ technology for 6 months averaged 71 percent compared to 59 percent for participants in the control group using SAP alone ($p<0.0001$). During the overnight period, sensor time in range with Control-IQ technology averaged 76 percent compared to 59 percent in the control group ($p<0.0001$). Time spent with sensor glucose values above 180 mg/dL was 27 percent in those using Control-IQ technology compared to 39 percent in the control group ($p<0.001$). Sensor time spent below 70 mg/dL was 1.4 percent with Control-IQ technology compared to 1.9 percent in the control group ($p<0.001$), and sensor time spent below 54 mg/dL was 0.21 percent compared to 0.24 percent in the control group ($p=0.02$). These results were demonstrated in participants with and without prior insulin pump therapy experience. In addition to sensor time in range, those using Control-IQ technology also saw statistically significant improvements in HbA1c and reductions in mean glucose. One report of diabetic ketoacidosis (DKA) was reported in the Control-IQ study arm due to an infusion set issue. No severe hypoglycemia was reported in the study.

“We are excited to see the outcome of 15 years of research, and have a lot of people to thank for it, including Benton Mize, Antoine Robert, Patrick Keith-Hines, Stephen Patek, Colin Steele, and Chad Rogers at Type Zero Technologies, who were instrumental in transitioning the system from academia to the commercial application,” said Dr. Breton. “After the resounding success of the system in adolescents and adults last year in the DCLP3, it is very rewarding to see our younger participants in the DCLP5 benefit as well, and to the same extent.”

The iDCL program is funded by the NIH’s National Institute of Diabetes and Digestive and Kidney Diseases under grant DK108483; Tandem Diabetes Care partially funded the DCLP5 study.

Basal-IQ Predictive Low Glucose Suspend Technology Data

Real World Satisfaction with Basal-IQ Technology

Details from a longitudinal satisfaction study of commercial users of Basal-IQ technology were presented by Laurel Messer, RN, PhD, CDE, Assistant Professor of Pediatrics at the Barbara Davis Center for Diabetes at the University of Colorado Anschutz Medical Campus. This study included 541 commercial users with T1D/caregivers of T1D minors who completed the Diabetes Impact and Device Satisfaction (DIDS) questionnaire (11 items scored on 10-point Likert scales) prior to Basal-IQ start, and 2, 4, and 6-months post-initiation. The study included people switching from Multiple Daily Injections (MDI), non-Tandem insulin pumps, and current Tandem pump users. Study aims were to measure device satisfaction (e.g. ease of use, trust, perception of glucose control) and diabetes impact (e.g. perception of sleep quality, fear of lows, interference with daily activities). Basal-IQ technology increased device satisfaction in former MDI and non-Tandem pump users, and sustained satisfaction across all user groups. Additionally, a reduction in diabetes impact was observed by the midpoint of the study and sustained over 6 months for all user groups.

About Control-IQ Advanced Hybrid Closed Loop Technology

The t:slim X2 insulin pump with Control-IQ technology uses Dexcom G6 CGM values, in conjunction with other variables such as insulin on board, to predict sensor glucose levels 30 minutes ahead and adjust insulin delivery accordingly[2,3,4]. If glucose values are predicted to drop below 112.5 mg/dL, basal insulin delivery is reduced, and when predicted to be below 70 mg/dL, basal insulin delivery is stopped. If glucose values are predicted to be above 160 mg/dL in the next 30 minutes, basal insulin will be increased. If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates and delivers a correction bolus with a target of 110 mg/dL once an hour as needed. Control-IQ technology also offers optional settings for sleep and exercise that will change treatment values to better match the different physiologic needs during these activities.

About Basal-IQ Predictive Low Glucose Suspend Technology

The simple-to-use t:slim X2 insulin pump with Basal-IQ predictive low glucose suspend technology uses glucose values from an integrated Dexcom G6 continuous glucose monitor to predict and help prevent lows with zero fingersticks[2,3,4]. Basal-IQ technology uses CGM values to help reduce the frequency and duration of low-glucose events by predicting glucose levels 30 minutes ahead and suspending insulin if they are expected to drop below 80 mg/dL or if a CGM reading falls below 70 mg/dL. Insulin delivery resumes as soon as sensor glucose values begin to rise.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience. The Company takes an innovative, user-centric approach to the design, development and commercialization of products for people with diabetes who use insulin. Tandem manufactures and sells the t:slim X2 insulin pump with Control-IQ technology. The t:slim X2 pump is capable of remote feature updates using a personal computer. Tandem is based in San Diego, California.

Important Safety Information:

Caution: Federal (USA) law restricts the t:slim X2 insulin pump, the t:slim X2 pump with Basal-IQ technology, and Control-IQ technology to sale by or on the order of a physician. The t:slim X2 pump, the t:slim X2 pump with Basal-IQ technology, and Control-IQ technology are intended for single patient use. The t:slim X2 pump, the t:slim X2 pump with Basal-IQ technology, and Control-IQ technology are indicated for use with NovoLog or Humalog U-100 insulin.

t:slim X2 insulin pump: The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is indicated for use in individuals 6 years of age and greater. t:slim X2 insulin pump with Basal-IQ technology: When used with a compatible integrated continuous glucose monitor (iCGM), the t:slim X2 insulin pump with Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. The t:slim X2 pump with Basal-IQ technology is indicated for use in individuals 6 years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (iCGM, sold separately) and ACE pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. **Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 14 years of age and greater.**

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 55 pounds.

Control-IQ technology and the t:slim X2 pump with Basal-IQ technology are not indicated for use in pregnant women, people on dialysis, or critically ill patients. Users of the t:slim X2 pump, the t:slim X2 pump with Basal-IQ technology, and Control-IQ technology must: be able and willing to use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. For additional important safety information, visit tandemdiabetes.com/safetyinfo.

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Forward-Looking Statement

This press release 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, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements relate to, among other things, the implications of the iDCL Trial on the future of closed-loop insulin delivery technology, the planned submission of data from the DCLP5 study in a regulatory filing with the FDA, and our ability to accelerate innovation and bring insulin delivery solutions that provide improved clinical outcomes to people with diabetes within particular timeframes or at all. These statements are subject to numerous risks and uncertainties and our actual results may differ significantly from those expressed or implied by these statements. For instance, the t:slim X2 pump with Control-IQ technology may not provide the expected benefits to people with diabetes or may have unforeseen negative effects; and competitive products or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable. Other significant risks and uncertainties include market acceptance of our existing products and products under development by physicians and people with diabetes; and possible future actions of the FDA or other regulatory body with respect to the Company's products; as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively, and other documents that we file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. We undertake no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

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[1] As measured by CGM

[2] If glucose alerts and CGM readings do not match symptoms or expectations or if taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.

[3] Dexcom G6 CGM sold separately

[4] The Dexcom G6 CGM transmitter can only be paired with one medical device (either a Dexcom receiver or t:slim X2 pump) and one consumer device (phone or tablet) at the same time.

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