TANDEM INVESTOR CENTER

CORRECTING and REPLACING Tandem Diabetes Care Reports Positive Results From Two Studies of the t:slim X2 Insulin Pump With Control-IQ Technology

June 13, 2019

Significant Time-in-Range Improvements Demonstrated in Adult and Pediatric Age Groups

SAN FRANCISCO--(BUSINESS WIRE)--Jun. 13, 2019-- Fourth paragraph, fourth sentence of release dated June 9, 2019, should read: 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 time spent below 54 mg/dL was 0.21 percent compared to 0.24 percent in the control group (p=0.02) (instead of 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 time spent below 54 mg/dL was 0.32 percent compared to 0.21 percent in the control group (p=0.02)).

The corrected release reads:

TANDEM DIABETES CARE REPORTS POSITIVE RESULTS FROM TWO STUDIES OF THE T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY

Significant Time-in-Range Improvements Demonstrated in Adult and Pediatric Age Groups

Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced positive results from two studies of the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed-loop technology. Data from both studies demonstrated that the system achieved the primary outcome of increasing time in range (70-180 mg/dL) without any severe hypoglycemic events. The t:slim X2 insulin pump with Control-IQ technology utilizes Dexcom G6 continuous glucose monitoring (CGM) sensor values to predict glucose levels and adjust insulin delivery to prevent highs and lows, while still allowing the user to manually bolus for meals. The system also automates correction boluses, which is a feature not commercially available today on automated insulin delivery devices.

Details from the two studies, which included Protocol 3 (DCLP3) of the National Institutes of Health (NIH)-funded International Diabetes Closed Loop (iDCL) trial and interim data from the Freelife Kid AP study, were presented today at the 79th Scientific Sessions of the American Diabetes Association (ADA) in a session moderated by Dr. Boris Kovatchev, Director of the Center for Diabetes Technology at the University of Virginia and principal investigator of the iDCL Trials. Presenters included Dr. Sue Brown, Associate Professor at the Center for Diabetes Technology at the University of Virginia and the endocrinologist who served as the protocol chair for this trial, and Dr. Eric Renard, Division Chief of Diabetic Medicine at University Hospital Center of Montpellier and the principal investigator for the Freelife Kid AP study.

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

The NIH-funded DCLP3 study is the first large-scale, 6-month 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, 168 patients with type 1 diabetes ages 14 and up were randomized 2:1 to Control-IQ technology (n=112) or sensor-augmented pump (SAP) therapy (n=56) and followed for 26 weeks. The entry HbA1c for participants in the study ranged from 5.4 to 10.6 with a mean of 7.4 percent. Approximately 20 percent of participants were new to pump therapy and the large majority were already using a CGM. All participants completed the study.

Glycemic Control – Time in range (70 mg/dL – 180 mg/dL) for participants using Control-IQ technology for 6 months was 71 percent per day compared to 59 percent per day for participants in the control group using SAP alone (p<0.0001). During the overnight period, time in range with Control-IQ technology was 76 percent compared to 59 percent in the control group (p<0.0001). Time spent with 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). 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 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 people with and without prior experience with insulin pump therapy. In addition to time in range, those using Control-IQ technology also saw statistically significant improvements in HbA1cand reductions in mean glucose. One report of diabetic ketoacidosis (DKA) was reported in the Control-IQ study arm due to an infusion set failure. No severe hypoglycemia was reported in the study.

System Performance and Usability - The system operated in active closed-loop mode an average of 92 percent of the time. Those using Control-IQ technology also participated in a technology acceptance survey to assess the impact the system had in their lives, and their general feelings about how simple or burdensome they found the technology. On a five-point scale, with 1 representing “not at all” and 5 representing “extremely”, participants rated the Control-IQ system a 4.8 for desire to continue use of the system, 4.7 for ease of use, 4.6 for usefulness and, 4.5 for trust.

“The contributions of the iDCL Trial to the body of automated insulin delivery research and its implications for the future of closed-loop technology is invaluable to the diabetes community,” said Dr. Kovatchev. “The NIH have provided an incredible service with their forward-thinking approach and support for this enormous undertaking.”

The iDCL trial was funded by the NIH’s National Institute of Diabetes and Digestive and Kidney Diseases under grant DK108483.

Freelife Kid AP Study Results

The Freelife Kid AP study is a multi-center, randomized assessment of the efficacy of closed-loop insulin therapy in prepubertal children, comparing nocturnal and 24-hour use of Control-IQ technology over 18 weeks, followed by an 18-week extension. The completed study, taking place in France, is expected to include 120 participants with type 1 diabetes ages 6 to 12 years old. An interim analysis was planned after 12 weeks from the first 30

included subjects to assess percent of time in closed-loop mode, incidence of any severe adverse events and efficacy measures based on CGM data.

Glycemic Control –Time in range (70 mg/dL – 180 mg/dL) at 12 weeks for participants using the Control-IQ feature full time increased from 60 percent to 72 percent per day overall ($p<0.001$) and 83 percent during the overnight period. Time spent with glucose values above 180 mg/dL was reduced from 36 percent to 25 percent ($p<0.001$), and time spent below 70 mg/dL was reduced from 4 percent to 3 percent ($p=0.006$). In addition to time in range, study participants using Control-IQ technology full time also saw a reduction in mean glucose. No severe hypoglycemia was reported.

System Performance - The system operated in active closed-loop mode an average of 97 percent of the time in the group using the Control-IQ feature 24 hours per day.

“Waking up with glucose levels in control decreases the risk of both high and low blood glucose throughout the entire day, so the improvements in time in range seen in these studies using Control-IQ technology, particularly in the overnight period, are extremely compelling,” said Dr. Renard. “But not only do new hybrid closed-loop systems need to be effective at improving glycemic control, they must also be easy to understand and use so patients can experience the full benefits of the technology. The t:slim X2 insulin pump with Control-IQ technology easily achieved both of these objectives.”

About the t:slim X2 Insulin Pump with Control-IQ Technology

The t:slim X2 insulin pump with Control-IQ technology utilizes Dexcom G6 CGM sensor values to predict glucose levels 30 minutes ahead and adjust insulin delivery to help prevent highs and lows, while still allowing the user to manually bolus for meals. The system also automates correction boluses, which is a feature not commercially available today on automated insulin delivery devices. Control-IQ technology was created from a series of algorithms developed by TypeZero Technologies, now a wholly owned subsidiary of Dexcom, from initial research conducted at the University of Virginia. Tandem entered in to a worldwide, non-exclusive license for use of TypeZero’s technology in July 2016. Prior to this, a phone-based system running the TypeZero algorithms had been used in over 30 clinical studies that included more than 450 participants.

“The Control-IQ technology data presented today are a testament to our commitment to offer customers simple-to-use products that deliver superior performance,” said John Sheridan, president and CEO of Tandem Diabetes Care. “We plan to submit data from the DCLP3 study in a regulatory filing to the FDA in the coming weeks and continue to prepare for commercial launch of the t:slim X2 with Control-IQ technology in the second half of 2019, subject to FDA approval.”

“Combining Tandem’s t:slim X2 pump with Control-IQ technology and the exceptional accuracy of our Dexcom G6 CGM which requires zero fingersticks for operation has delivered what promises to be the most advanced, simple-to-use hybrid closed-loop system to date,” said Kevin Sayer, president and CEO of Dexcom. “The impressive data released today, combined with our iCGM classification, will help to accelerate innovation and bring powerful insulin delivery tools to people with diabetes more quickly.”

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’s flagship product, the t:slim X2 insulin pump, is capable of remote software updates using a personal computer and features integrated continuous glucose monitoring. Tandem is based in San Diego, California.

The content in this release is the sole responsibility of the authors and does not necessarily represent the official views or imply endorsement of the National Institutes of Health.

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 and Freelife Kid AP study on the future of closed-loop insulin delivery technology, the expected number of participants in the remainder of the Freelife Kid AP study and the outcomes of this study, the planned submission of data from the DCLP3 study in a regulatory filing with the FDA, the anticipated commercial launch of the t:slim X2 insulin pump with Control-IQ technology, and our ability to accelerate innovation and bring insulin delivery tools 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, we may encounter challenges that could delay or prevent the commercial launch of the t:slim X2 insulin pump with Control-IQ technology; 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; there may be challenges in successfully completing ongoing clinical studies on the timeline we expect or at all; 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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