TANDEM INVESTOR CENTER

Tandem Diabetes Care Announces NEJM Publication of Pediatric Study Demonstrating Increased Time-In-Range using the t:slim X2 Insulin Pump with Control-IQ Technology

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SAN DIEGO--(BUSINESS WIRE)--Aug. 27, 2020-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced publication by the *New England Journal of Medicine* (NEJM) of results from the Protocol 5 study (DCLP5) of the International Diabetes Closed Loop (iDCL) trial. Results demonstrated increased time spent in range (70-180 mg/dL) in children ages 6 to 13 years old using the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed-loop technology. The article was published on August 27, 2020 and is available on the journal website, www.NEJM.org.

The DCLP5 study was the first-ever large-scale, closed-loop pediatric study that included a dedicated control group. Over the four-month study period, use of Control-IQ technology led to a higher percentage of time spent in range (70-180 mg/dL) and less hyperglycemia than the control group. The control group used either a sensor augmented pump without automated insulin dosing or Tandem's t:slim X2 pump with Basal-IQ® predictive low glucose suspend technology. No severe hypoglycemia or diabetic ketoacidosis was reported, and 100 percent of participants using Control-IQ technology completed the study.

"We are thrilled with the benefits observed in this study in school-aged children with type 1 diabetes, a population that often struggles with diabetes management for a variety of reasons," said Dr. R. Paul Wadwa, Professor of Pediatrics, at the Barbara Davis Center for Diabetes, University of Colorado Anschutz Medical Campus, and the protocol chair for this trial. "Control-IQ technology proved very easy to use for children and their parents and led to improved glucose control during both the day and night."

"After the resounding success of the system in adolescents and adults in the previous DCLP3 study, it is very rewarding to see younger participants in the DCLP5 benefit as well, and to the same extent," said Dr. Marc Breton, the Associate Director for Research of The Center for Diabetes Technology at the University of Virginia, and the Principal Investigator of the DCLP5 study. "We are excited to see the results of 15 years of research acknowledged once more by NEJM."

The t:slim X2 insulin pump with Control-IQ technology utilizes Dexcom G6 continuous glucose monitoring (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 delivers automatic correction boluses, a first for commercial automated insulin delivery systems. The t:slim X2 insulin pump with Control-IQ technology, originally approved for ages 14 and older, received U.S. Food and Drug Administration clearance for use in ages six and older in June 2020. The t:slim X2 pump with Control-IQ technology also recently launched in select geographies outside the United States.

"The safety and efficacy data from the DCLP5 study featured in this NEJM publication, coupled with the positive experiences reported to us by younger Control-IQ users and their families, exemplifies our commitment to our mission to improve the lives of people with diabetes," said John Sheridan, president and CEO of Tandem Diabetes Care.

"The integration of Control-IQ technology with Dexcom G6 has proven to be an incredibly effective combination for automated insulin delivery. We are thrilled with the pediatric results published today and proud of the role Dexcom played in the DCLP5 study," said Kevin Sayer, chairman, president and CEO of Dexcom.

Key Data Highlights

Glycemic Control over Four Months

- Time in range (70 mg/dL – 180 mg/dL) increased from 53 percent at baseline to 67 percent in participants using Control-IQ technology, the equivalent of 3.4 more hours per day. The control group demonstrated an increase from 51 percent to 55 percent.
- Time in range at night (midnight to 6:00 a.m.) was 80 percent using Control-IQ technology compared to 54 percent in the control group.
- Mean glucose was significantly lower in participants using Control-IQ technology (162 vs. 179 in the control group, $p<0.001$)
- In both groups, time <70 mg/dL was very low (median 1.6 percent in the Control-IQ group and 1.8 percent in the control group). Two thirds of the control group participants used the t:slim X2 insulin pump with Basal-IQ technology, a predictive low-glucose suspend feature that has been demonstrated to reduce hypoglycemia. No severe hypoglycemia was reported.
- Time spent above 180 mg/dL was 31 percent using Control-IQ technology compared to 43 percent in the control group ($p<0.001$).
- Control-IQ technology demonstrated benefits across a broad range of baseline characteristics including age, sex, body mass index, household income, parental education, previous insulin pump or injection use, and baseline glycated hemoglobin.
- The treatment effect was evident in the first month and appeared consistent over 4 months.

System Performance and Usability

- The median time the system was in active closed-loop mode was 93 percent.

- The median time the Dexcom G6 CGM was in use was 96 percent.
- The 16-week trial was completed by all participants using Control-IQ technology.

The DCLP5 study was a 4-month, randomized, controlled, multi-center study. Following a two to four-week run-in period, the length of which was determined based on previous pump and CGM experience, 101 patients with type 1 diabetes ages 6-13 years were randomized 3:1 to Control-IQ technology (n=78) or to the control group (n=23) and followed for 16 weeks. Two thirds of the control group used a sensor augmented pump with Tandem's t:slim X2 pump with Basal-IQ predictive low glucose suspend technology and the remainder used a sensor augmented pump without automated insulin dosing. The entry HbA1c for participants in the study ranged from 5.7 percent to 10.1 percent with a mean of 7.6 percent in the Control-IQ group and 7.9 percent in the SAP group. Approximately 20 percent of participants were new to pump therapy and all but 8 percent were already using a CGM. There were no exclusion criteria based on hemoglobin A1c (HbA1c), history of acute complications, or previous experience using an insulin pump or CGM.

This study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through grant UC4DK108483 and Tandem Diabetes Care, Inc.

Reference:

Breton MD, Kanapka LG, Beck RW, et al. A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes. *N Engl J Med.* 2020;383:836-45. DOI: 10.1056/NEJMoa2004736

Results from the Protocol 3 study (DCLP3) of the iDCL trial studying use of the t:slim X2 insulin pump with Control-IQ technology in ages 14 and up were published by NEJM last year, and announced by Tandem via press release on October 16, 2019.

About the t:slim X2 Insulin Pump

The simple-to-use t:slim X2 insulin pump includes advanced features like a large color touchscreen, rechargeable battery, *Bluetooth*® wireless technology, USB connectivity and watertight construction (IPX7)[1]. It is capable of remote software updates using a personal computer, offering the potential for users to access new features as necessary regulatory requirements are met.[2] The t:slim X2 pump is up to 38 percent smaller than other insulin pumps and holds up to 300 units of insulin.[3] The t:slim X2 pump was the first insulin pump classified by the FDA in a new device category called alternate controller enabled (ACE) infusion pumps and the first system approved as compatible with interoperable continuous glucose monitoring (iCGM) devices.

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. Tandem 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.

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[1] Tested to a depth of 3 feet for 30 minutes

[2] Future algorithms and integrations with compatible devices may not be developed and would be subject to applicable regulatory requirements. A prescription and additional training may be required to access certain future software updates. Charges may apply.

[3] 38 percent smaller than MiniMed 630G and 670G and at least 28 percent smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.

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