TANDEM INVESTOR CENTER

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

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SAN DIEGO--(BUSINESS WIRE)--Oct. 16, 2019-- 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 landmark Protocol 3 study (DCLP3) of the National Institutes of Health (NIH)-funded International Diabetes Closed Loop (iDCL) trial using the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed-loop technology. The DCLP3 study was the first-ever large-scale, six-month closed-loop study that included a dedicated control group. Over the six-month study period, use of Control-IQ technology led to a higher percentage of time spent in range (70-180 mg/dL), less hyper- and hypoglycemia and better HbA1c levels than use of a sensor augmented pump. No severe hypoglycemic events were reported, and 100 percent of participants completed the study. The article was published today on the journal website, NEJM.org, and will appear in the October 31, 2019 printed issue.

The t:slim X2 insulin pump with Control-IQ technology, currently under review by the U.S. Food and Drug Administration (FDA), 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, which is a feature not commercially available today on automated insulin delivery devices.

“This NEJM publication recognizes the importance and rigor of the landmark DCLP3 study and the robustness of the safety and efficacy data behind the t:slim X2 insulin pump with Control-IQ technology,” said John Sheridan, president and CEO of Tandem Diabetes Care. “These outcomes, combined with the overwhelmingly positive experiences reported by trial participants, give us confidence that availability of Control-IQ technology will further our mission to improve the lives of people with diabetes, and we continue to prepare for its commercial launch this year, pending FDA approval.”

“We are thrilled with the results published today and proud of the role Dexcom played in the DCLP3 study,” said Kevin Sayer, Chairman, President and Chief Executive Officer at Dexcom. “Consistent use and exceptional sensor accuracy are critical components for optimized glucose control in an advanced hybrid closed loop system. As the study’s greater than 90 percent average time in closed loop demonstrates, Dexcom’s G6 excels on both of these fronts. The integration of Control-IQ technology with Dexcom’s G6 has proven to be a powerful combination for automated insulin delivery.”

Key Data Highlights

Glycemic Control over Six Months

- Time in range (70 mg/dL – 180 mg/dL) increased from 61 percent at baseline to 71 percent using Control-IQ technology. The control group using sensor-augmented pump therapy alone, remained unchanged at 59 percent ($p<0.0001$). This mean difference amounted to 2.6 more hours per day spent in the target range.
- Time in range at night (midnight to 6:00 a.m.) was 76 percent using Control-IQ technology compared to 59 percent using a sensor-augmented pump ($p<0.0001$).
- Time spent below 70 mg/dL was 1.6 percent using Control-IQ technology compared to 2.3 percent using a sensor-augmented pump ($p<0.001$). No severe hypoglycemia was reported.
- Time spent above 180 mg/dL was 27 percent using Control-IQ technology compared to 38 percent using a sensor-augmented pump ($p<0.001$).
- Statistically significant improvements in HbA1c and reductions in mean glucose were observed.

System Performance and Usability

- The median time the system was in active closed-loop mode was over 90 percent
- The median time the Dexcom G6 CGM was in use was 97 percent
- 100 percent of participants completed the study

The NIH-funded DCLP3 study was a 6-month, randomized multi-center study that included a dedicated control group. 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. There were no exclusion criteria based on hemoglobin A1c (HbA1c), history of acute complications, or previous experience using an insulin pump or CGM.

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

Reference:

Brown SA, Kovatchev D, Raghinaru JW, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *N Engl J Med*. 2019;381(18):1707-17. DOI: 10.1056/NEJMoa1907863

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 they meet necessary regulatory requirements.[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.

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 anticipated commercial launch of the t:slim X2 insulin pump with Control-IQ technology, the timing and outcome of regulatory approvals for the t:slim X2 with Control-IQ technology, and the ability of our products to improve customer satisfaction and clinical outcomes. These statements are subject to numerous risks and uncertainties, including the risks that regulatory agencies may fail to approve new product features or updates on our expected timeframe or at all, the real-world clinical benefits from use of Control-IQ technology may not match the results reported in the DCLP3 study and the level of customer satisfaction from the use of our products and features may be different from what we expect. In addition, we rely on numerous third-party suppliers, partners and licensors for the commercialization of the t:slim X2 with Control-IQ. Any disruption or delays by any of these third parties may adversely impact our commercial launch goals. We also may experience other risks identified in Tandem's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively, and other documents 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. Tandem undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

[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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