



Tandem Diabetes Care Announces Presentations Demonstrating Immediate and Sustained Real-World Improvements with Control-IQ Technology

June 4, 2021

SAN DIEGO--(BUSINESS WIRE)--Jun. 4, 2021-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, announced data presented this week on real-world use of the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed-loop technology at the 14th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD). Several presentations detailed positive outcomes, including a plenary session today by Boris Kovatchev, PhD, Director of the Center for Diabetes Technology at the University of Virginia, which demonstrated immediate and sustained improvements in time in range (TIR) in more than 9,000 people with diabetes who wore the system for 12 months.

"Experience matters in automated insulin dosing systems, and Control-IQ technology is performing as well in the real world as it did in the pivotal studies," said Dr. Jordan Pinsker, Medical Director at Tandem Diabetes Care. "Additionally, patient-reported outcomes, including reduced diabetes burden and improved sleep quality, demonstrate that our Control-IQ technology can make a positive and sustained impact on the lives of people with diabetes."

ATTD PRESENTATION SUMMARIES

Glycemic trends in people with type 1 diabetes based on their time of adoption of Control-IQ technology.

Session: 270 - Oral Presentation 08

Thursday, June 3, 2021 @ 20:30 - 21:40 CET

This presentation reported glycemic trends in people with type 1 diabetes based on their time of adoption of the t:slim X2 insulin pump with Control-IQ technology. Study sample included 6,233 people with type 1 diabetes who had initiated Control-IQ technology between its launch (January 15, 2020) and July 15, 2020. Participants were divided into three groups based on their time of adoption: within four weeks of launch (Group A), between 3-4 months (Group B) and 5-6 months (Group C). Irrespective of when Control-IQ technology was adopted, significant improvements in sensor TIR were experienced by all groups.

Quality of life outcomes and glycemic control from the t:slim X2 pump with Control-IQ technology – real-world observations from the CLIO study.

Session: 360 - Oral Presentation 11

Friday, June 4, 2021 @ 17:15 - 18:25 CET

This presentation reported outcomes from the ongoing Control-IQ Observational (CLIO) Study evaluating real-world use of the t:slim X2 insulin pump with Control-IQ technology in diverse groups of people with type 1 diabetes. The study sample included 700 participants from diverse ethnic groups who had uploaded at least 21 days of pump data to the t:connect™ web application (Tandem Diabetes Care, US only) and had at least 75 percent CGM use during this time. Participants completed patient-reported outcome measures at baseline and three months after study start. Continued use of t:slim X2 pump with Control-IQ technology resulted in sensor time in range of 72.5 percent (median, IQR=71-73 percent) and sensor time <70 mg/dl of 1.1 percent (median, IQR=1.3-1.2 percent). In conjunction with improved glycemic profiles, data from validated quality of life survey measures completed by participants at baseline and three months showed significant reductions in diabetes impact and greater satisfaction with Control-IQ technology compared to their prior insulin delivery devices.

Plenary Session: Advances in Closed-Loop Systems – Lessons Learnt from Clinical Studies.

Plenary Session 03

Friday, June 4, 2021 @ 18:30 - 20:05 CET

Boris Kovatchev, Ph.D. from the University of Virginia Centers for Diabetes Technology presented outcomes from 12 consecutive months of real-world Control-IQ technology use, representing more than 1 billion data points analyzed. Results showed an overall median Time in Range of 73.6% (increase of 10% from baseline, 63.6%), mirroring results from the pivotal trials. The median percent time in automation or "closed-loop" was 94.2%. Median percent time below 70 mg/dL remained constant at approximately 1%.

Corporate Symposium: Catching Some ZZZ's. A symposium on user experience and clinical outcomes with the t:slim X2 insulin pump with Control-IQ technology.

Friday, June 4, 2021 @ 17:15-18:15 CET

This symposium featured three short talks, providing insights and information on the Control-IQ algorithm and system performance, patient-reported outcomes on quality of life, and implications for clinical practice. Real-world analysis of more than 72,000 individuals using Control-IQ technology showed significant improvements in nighttime glycemic control. Validated patient-reported outcomes measures were used to qualitatively confirm a decrease in diabetes burden and increase in device satisfaction. Specific case studies provided guidance for practitioners on ways to optimize patient expectations and experience.

A recording of the corporate symposium is available at <https://www.tandemdiabetes.com/providers/connect-with-us/events>.

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.^{1,2,3} Control-IQ technology is designed to increase sensor time in range by automatically increasing, decreasing, or stopping insulin delivery, or giving an automatic correction bolus based on predicted glucose levels. 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 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 and is the only automated insulin dosing device approved for children as young as six years old. Tandem is based in San Diego, California.

Important Safety Information:

The t:slim X2 insulin pump with Control-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Control-IQ technology, and a compatible continuous glucose monitor (CGM, sold separately). The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When used with a compatible CGM, the System can be used to automatically increase, decrease, and suspend delivery of basal insulin based on CGM sensor readings and predicted glucose values. The System can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The pump and the System are indicated for use in individuals six years of age and greater. The pump and the System are intended for single user use. The pump and the System are indicated for use with NovoRapid or Humalog U-100 insulin. The System is intended for the management of Type 1 diabetes.

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 25 kilograms.

The System is not indicated for use in pregnant women, people on dialysis, or critically ill users. Do not use the System if using hydroxyurea.

Users of the pump and the System must: be willing and able 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 and the CGM transmitter and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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¹ 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.

² Dexcom G6 CGM sold separately.

³ 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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