

Tandem Diabetes Care Presents Positive Real-world Data from Automated Insulin Delivery Systems at American Diabetes Association Scientific Sessions

June 13, 2020

SAN DIEGO--(BUSINESS WIRE)--Jun. 13, 2020-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today presented positive real-world data from early use of the t:slim X2™ insulin pump with Control-IQ™ advanced hybrid closed loop technology, demonstrating statistically significant improvements in sensor Time in Range (70-180 mg/dL) in people living with both type 1 and type 2 diabetes with no increase in hypoglycemia (<70 mg/dL). The data was presented in two separate poster presentations this morning during the 80th Scientific Sessions of the American Diabetes Association.

"We are proud to see that early adopters of Control-IQ technology are experiencing real-world outcomes consistent with or better than those observed in the pivotal study," said John Sheridan, president and CEO of Tandem Diabetes Care. "We are also thrilled to see positive outcomes being presented by independent investigators from clinical research using our automated insulin delivery systems in pediatric populations."

Control-IQ Hybrid Closed Loop Technology Presentations

Control-IQ Technology in the Real World: The First 30 Days

Poster Presentation (95-LB)

Category: 12-D Clinical Therapeutics/New Technology—Insulin Delivery Systems

This poster reported outcomes from a retrospective analysis of users who uploaded at least 30 days of data to the t:connect® web application before and after initiation of Control-IQ technology as of March 11, 2020 and had at least 75 percent continuous glucose monitoring (CGM) use during this time (n=1,659). Use of Control-IQ technology led to a 10 percent increase (p<0.001) in median sensor Time in Range (70-180 mg/dL) to 78 percent, due to a 10 percent decrease in sensor time >180mg/dL and a 0.1 percent decrease of sensor time <70mg/dL. Users experienced 96 percent time in closed loop automation.

Glycemic Outcomes for People with Type 1 and Type 2 Diabetes Using Control-IQ Technology: Real World Data from Early Adopters Poster Presentation (126-LB)

Category: 12-F Clinical Therapeutics/New Technology—Other Therapeutic Agents

This poster reported outcomes from a retrospective analysis of users who uploaded at least 14 days of data to the t:connect web application before and after initiation of Control-IQ technology as of March 11, 2020 and had at least 75 percent CGM use during this time. People with type 1 diabetes (n=2,896) showed a 9 percent increase in median sensor Time in Range (p<0.001), and a 0.04 percent decrease in sensor time <70 mg/dL (<0.001). Users with type 2 diabetes (n=144) experienced a 6 percent increase in median sensor Time in Range (p<0.001). Median time spent <70 mg/dL remained unchanged (0.2 percent). Both groups experienced 96 percent time in closed loop automation.

Upcoming Basal-IQ Predictive Low Glucose Suspend Technology Presentation

Reduction in Self-Reported Adverse Events Related to Severe Hypoglycemia in Individuals Using A Predictive Low Glucose System: Results from a Real-World Setting

Oral Presentation (267-OR) Session: Hypoglycemia – Guts and Garters Monday, June 15, 2020 at 9:15 a.m. Central Time

This presentation will review reductions in self-reported adverse events related to severe hypoglycemia, including paramedic visits, emergency room visits and hospital admissions.

About Control-IQ Advanced Hybrid Closed Loop Technology

The t:slim X2 insulin pump with Control-IQ technology uses glucose values from an integrated Dexcom G6 CGM, 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}. 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 up to 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 CGM to predict and help prevent lows with zero fingersticks^{1,2,3}. 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.

Important Safety Information:

RX ONLY. 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.

teslim X2 insulin pump: The teslim 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. testim X2 insulin pump with Basal-IQ technology: When used with a compatible integrated continuous glucose monitor (iCGM, sold separately), the testim X2 insulin pump with Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. The testim X2 pump with Basal-IQ technology is indicated for use in individuals 6 years of age and greater. Control-IQ technology is intended for use with an 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.

BOXED 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.

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.

Tandem Diabetes Care, t:connect, and Basal-IQ are registered trademarks, and t:slim X2 and Control-IQ are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. All other third-party marks are the property of their respective owners.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200613005006/en/

Tandem Diabetes Care Contact Information:

Media: Steve Sabicer, 714-907-6264, sabicer@thesabicergroup.com
Investors: Susan Morrison, 858-366-6900 x7005, lR@tandemdiabetes.com

Source: Tandem Diabetes Care

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.