Tandem Diabetes Care Announces Control-IQ Technology Meta-analysis Demonstrating Positive Clinical Impact of Automatic Correction Bolusing on Glucose Control in People with Type 1 Diabetes

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SAN DIEGO--(BUSINESS WIRE)--Apr. 17, 2023-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced publication by *Diabetes Technology & Therapeutics* of a meta-analysis of three randomized controlled trials of its Control-IQ advanced hybrid closed-loop technology. Results demonstrate the positive clinical impact of the system's automatic correction bolusing on glucose control across a wide range of ages and demographics of people living with type 1 diabetes. People with the highest baseline blood sugar levels experienced the greatest benefit from the auto-bolus feature of the Control-IQ algorithm. Automatic correction bolusing is an automated insulin dosing feature that is only commercially available in the t:slim X2 insulin pump with Control-IQ technology. All participants were using a Dexcom G6 Continuous Glucose Monitoring (CGM) System.

The analysis showed an average increase in time in range* of 2.8 hours and a reduction in hemoglobin A1c compared to control groups in people ages 2 to 72 years old.** Improvements in time in range for subjects using Control-IQ technology (n=256) were immediate, sustained, and observed across the spectrum of patient characteristics including age, race-ethnicity, parental education, family income, baseline glycated hemoglobin level, virtual vs. in-person training format, and pre-study insulin delivery method. The majority of the control group (n=113) used an insulin pump (91%), some with predictive low glucose suspend technology.

"Control-IQ technology delivered the most robust improvements in those entering the study with the highest hemoglobin A1c and lowest time in range," said Roy W. Beck, MD, PhD, Executive Director of the Jaeb Center for Health Research. "The high number of automatic boluses given by the system in this group likely reflect previously missed meal boluses or lack of manual correction boluses when on conventional therapy and demonstrates the substantial impact Control-IQ technology's auto-bolusing feature can have for people struggling on a standard pump or multiple daily injections."

"All subgroups in these studies, regardless of age, ethnicity, education, or previous pump experience, benefited from Control-IQ technology," said Boris Kovatchev, PhD, Director of the Center for Diabetes Technology at the University of Virginia. "It is clear from these results, which are consistent with real-life data from thousands of current Control-IQ technology users, that this technology should be considered as an option for anyone living with type 1 diabetes."

"With three randomized, controlled trials completed, Control-IQ technology has the most robust data set supporting its benefits compared to any other automated insulin delivery system available today," said Jordan Pinsker, MD, Vice President and Medical Director at Tandem Diabetes Care.

Additional Data Highlights

Glycemic Control at 3 Months

- Mean time in range with Control-IQ technology increased from 57 percent at baseline to 70 percent during follow-up compared to 56 percent to 57 percent in the control group, for a mean adjusted difference of 11.5 percent.
- Hemoglobin A1c decreased from 7.5 percent at baseline to 7.0 percent for the Control-IQ technology group, with an adjusted improvement of 0.38 percent compared to the control group.
- Substantial daytime and nighttime reductions in hyperglycemia (>250 mg/dL) and mean glucose were seen with Control-IQ technology compared with the control group. The greatest difference in mean glucose was between 4am and 8am.
- Time spent in hypoglycemia (<70 mg/dL) was low at baseline, but reductions in time <70 mg/dL and <54 mg/dL were still observed with Control-IQ technology compared with the control group.
- The rate of severe hypoglycemia events was exceedingly low (~2 per 100 person-years) and similar between Control-IQ technology and the control group.

System Performance and Useability

- Fewer user-initiated boluses (meal and correction) were associated with people age 14 to 24 years and those with a baseline hemoglobin A1c of 8 percent or higher. Fifty percent or more of the total number of daily boluses for these two groups were automated.
- The median time the system was in active closed loop was 93 percent.
- Results were observed regardless of pre-study experience with an insulin pump.

Publication Reference:

Beck RW, Kanapka, LG, Breton, MD, et al. A Meta-Analysis of Randomized Trial Outcomes for the t:slim X2 Insulin Pump with Control-IQ Technology in Youth and Adults from Age 2 to 72. *Diabetes Technol Ther*. 2023;25(5):1-14. DOI: 10.1089/dia.2022.0558

Results from the Protocol 3 study (DCLP3) of the International Diabetes Closed Loop (iDCL) trial evaluating the use of Control-IQ technology in ages 14 and up, from the Protocol 5 study (DCLP5) of the iDCL trial studying use in ages 6 to 13, and from the Pediatric Artificial Pancreas (PEDAP) Clinical Trial were published by the *New England Journal of Medicine* in October 2019, August 2020, and March 2023, respectively.

The three studies included in this meta-analysis were funded by the National Institute of Diabetes and Digestive and Kidney Diseases (DCLP-3 and DCLP-5 through grant UC4DK108483, and PEDAP through grant U01DK127551). Product support for all was provided by Tandem Diabetes Care and Dexcom, Inc.

* Time in range is defined as 70-180 mg/dL and is measured by CGM.
** The algorithm used in the study for ages 2-5 was identical to the commercial version of Control-IQ technology, except for the ability to enter a lower body weight and total daily insulin value at system initialization.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc., a global insulin delivery and diabetes technology company based in San Diego, California, creates new possibilities for people living with diabetes, their loved ones, and healthcare providers through a positively different experience. The company's human-centered approach to design, development, and support delivers innovative products and services for people who use insulin. Tandem manufactures and sells the t:slim X2 insulin pump with Control-IQ technology. For more information, visit tandemdiabetes.com.

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Forward-looking Statements

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. These forward-looking statements relate to, among other things, our goal to establish that Control-IQ technology's automatic correction bolusing feature could be a powerful therapy management tool for people from age 2 to 72 with type 1 diabetes. . These forward-looking statements are subject to numerous risks and uncertainties, including risks associated with the research and development process generally, such as the design, testing and validation of products and related systems in compliance with applicable regulatory and legal requirements in the markets that we serve, the real-world clinical benefits from use of Control-IQ technology may not match the results reported in the studies or controlled trials and the level of customer satisfaction from the use of our products and features may be different from what we expect, our ability to develop, scale and maintain systems, personnel and infrastructure to support customers across diverse geographies and market segments, as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, 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. Actual results could differ materially from those anticipated or projected in the forward-looking statements. 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.

Responsible use of Control-IQ technology

Control-IQ technology does not prevent all highs and lows. Users must still bolus for meals and actively manage their diabetes. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

Important Safety Information: RX ONLY. The t:slim X2 pump and Control-IQ technology are intended for single patient use. The t:slim X2 pump and Control-IQ technology are indicated for use with U-100 insulin only. t:slim X2 insulin pump: The t:slim 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 t:slim X2 pump is indicated for use in individuals six years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (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 six years of age and greater.

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 is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and Control-IQ technology must: 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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