Tandem Diabetes Care Study Demonstrates Improvements of All Clinical Endpoints in Adults with Type 2 Diabetes Using Control-IQ Technology

November 10, 2022

SAN DIEGO--(BUSINESS WIRE)--Nov. 10, 2022-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, announced results from a prospective, multicenter, single-arm study of adults living with type 2 diabetes who achieved improvement in all clinical endpoints with the use of the t:slim X2 insulin pump with Control-IQ technology.[1]

Presented today at the 22nd Annual Diabetes Technology Meeting, the data demonstrated the system to be safe during 6 weeks of use, with a substantial improvement in time in range and mean glucose related to a reduction in hyperglycemia and no increase in continuous glucose monitor (CGM)-measured hypoglycemia.* Both prior multiple daily injection (MDI) users and prior basal insulin only users showed similar levels of improvement. Study participants indicated a high level of satisfaction with the system.

“Our goal with this study was to show Control-IQ technology was safe and could offer considerable benefit to individuals with type 2 diabetes, and we accomplished that,” said Carol Levy, MD, CDCES, protocol chair for the study and Professor of Medicine (Division of Endocrinology, Diabetes and Bone Disease) at the Icahn School of Medicine at Mount Sinai. “The 15 percent time in range improvement from prior therapy represents a 3.6 hour/day increase in time in range, with no hypoglycemia events.”

“The results presented today are consistent with numerous studies that support the benefits of pump therapy to people who live with type 2 diabetes,” said Jordan Pinsker, MD, Vice President and Medical Director for Tandem Diabetes Care. “People living with type 2 diabetes often take other medications in combination with their insulin therapy. The combination of safety outcomes and high satisfaction scores seen in this population, who were able to continue these existing medications during the study, shows that Control-IQ technology could be a powerful management solution for their therapy needs."

Primary Outcomes

Glycemic Control

- Use of Control-IQ technology was demonstrated to be safe during 6 weeks of use
- Mean time in range across all participants improved 15 percentage points, an increase of 3.6 hours per day
- Mean time in range for prior MDI/pump users improved 16 percentage points
- Mean time in range for prior Basal-only insulin users improved 13 percentage points
- Mean Time >180 mg/dl improved 15 percentage points, which is a reduction of 3.6 hours per day
- Median time >250 improved 5.6 percentage points, which is a reduction of almost one hour per day
- No increase in CGM-measured hypoglycemia

System Performance and Usability

- Median time in closed loop was 96%
- Study participants indicated a high level of satisfaction with the system
- Majority of participants were using additional glycemic therapies other than insulin and continued their use during the trial

This multicenter, prospective trial included 30 adults with type 2 diabetes from three clinical centers: Icahn School of Medicine at Mount Sinai, New York City, NY; Mayo Clinic, Rochester, MN; and Texas Diabetes and Endocrinology, Austin, TX. The study was coordinated by the JAEB Center for Health Research, in Tampa, FL. Participants with type 2 diabetes (mean age 54±12 years, mean HbA1c 8.6±1.2, median BMI 31) using either MDI (N=15), pump (N=2), or basal without bolus insulin (N=13) collected unblinded CGM data (baseline) followed by an open-loop period prior to initiating use of Control-IQ technology for 6 weeks.

Please note Control-IQ technology is not approved for use in individuals with type 2 Diabetes. This study was conducted with an investigational device exemption with a modified pump.

*Time in range is defined as 70-180 mg/dL.

[1] Levy CJ, Raghinaru D, Kudva Y, et al. Significant Reduction in Hyperglycemia and High Satisfaction with Use of Control-IQ Technology in Prior MDI and Basal Only Insulin Users with Type 2 Diabetes (T2D). Poster presented at 22nd Annual Diabetes Technology Meeting; November 10, 2022; Virtual.

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 could be a powerful management solution for therapy needs of individuals living with type 2 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, 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.

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.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #tslimX2, #2022DTM and #TNDM.

Follow Tandem Diabetes Care on Facebook at facebook.com/TandemDiabetes.

Follow Tandem Diabetes Care on LinkedIn at linkedin.com/company/tandemdiabetes.

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.

Indications for Use:

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 pump is indicated for use in individuals six years of age and greater. The pump is intended for single patient home use and requires a prescription. The pump is indicated for use with U-100 insulin only.

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. Control-IQ technology is intended for single patient use. Control-IQ technology is indicated for use with U-100 insulin only.

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.

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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