Tandem Diabetes Care Announces NEJM Publication of Positive Pivotal Study Outcomes with Control-IQ+ AID Technology in Type 2 Diabetes

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– Additional data presented at the 18th International Conference on Advanced Technologies & Treatments for Diabetes –

SAN DIEGO--(BUSINESS WIRE)--Mar. 19, 2025-- 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 positive results from the company's pivotal trial of Control-IQ+ automated insulin delivery (AID) technology in people with type 2 diabetes. The article is now available on the journal website, www.NEJM.org. Additional study findings were presented today during a symposium at the 18th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD) in Amsterdam, the Netherlands.

Results published in NEJM demonstrate significant improvements in time in range and hemoglobin A1c (A1C) in people with type 2 diabetes when using Control-IQ+ technology compared to a control group (CGM group) who continued their pre-study insulin delivery method in conjunction with a continuous glucose monitoring (CGM) system. A reduction in A1C of 0.9% was observed in people using Control-IQ+ technology (N=215) compared with 0.3% in the CGM group (N=104). A1C reduction of 2.3% was observed with Control-IQ+ in people entering the study with an A1C of 9% or higher. These improvements were seen across a racially and socio-economically diverse population spanning ages 19 to 87 years old. Both groups used a Dexcom G6 CGM System for the duration of the study.

"This study represents the most rigorous evaluation of automated insulin delivery technology for people with type 2 diabetes ever conducted. The randomized controlled design and broad inclusion goals that did not limit participation based on A1C levels allowed us to truly determine the treatment effect of the algorithm," said Roy W. Beck, MD, PhD, medical director of the Jaeb Center for Health Research, who coordinated the study. "These results demonstrate the substantial value of Control-IQ+ technology for people with type 2 diabetes who use insulin. It was encouraging that even people using insulin plus a GLP-1 receptor agonist drug, such as Ozempic, had substantial A1C improvement with the addition of Control-IQ+ to their treatment regimen."

"The benefits of Control-IQ+ technology were evident across an incredibly diverse population, regardless of pre-study glycemic control or experience with diabetes technology. In fact, those with low and high numeracy scores at baseline did equally as well, suggesting that the technology was simple to use regardless of education level or their general understanding of diabetes," said Jordan Pinsker, MD, chief medical officer at Tandem Diabetes Care. "These results underscore the potential of this technology to improve outcomes for people living with type 2 diabetes who use insulin, while helping alleviate daily therapy burden and improve quality of life."

Study Design

The primary outcome of the 13-week study was to evaluate change in A1C with Control-IQ+ technology in adults ages 18 and older living with type 2 diabetes compared to a control group who continued their pre-study insulin regimen along with a real-time CGM system. Additional outcomes included changes in CGM-measured time in range, time in hyperglycemia, time in hypoglycemia, as well as safety events including severe hypoglycemia, diabetic ketoacidosis, and other serious adverse events.

The study included data from 319 participants across 21 clinical centers in the United States and Canada, including one U.S. Veterans Administration Hospital. The study population represents one of the most diverse studies of AID technology in type 2 diabetes with 39% of participants identifying as minority race or ethnicity, including 22% Black and 11% Hispanic. Nearly half (44%) were on a stable dose of a GLP-1 receptor agonist and 37% were on a stable dose of an SGLT-2 inhibitor, which they continued throughout the study. 40% used more than 100 units of insulin per day, and only 4% were using an insulin pump at baseline.

Importantly, participants came into the study with very varied insulin regimens. 75% of participants were using a form of fixed dosing to calculate meal boluses prior to joining the study. All participants were given the option to use simplified boluses by dosing with preset amounts of carbohydrate or units of insulin during the study (for example, small, medium or large meals).

Key Data Highlights Published by NEJM

Glycemic Control

- Mean A1C decreased by 0.9% with Control-IQ+, from 8.2% to 7.3%, and by 0.3% for the CGM group, from 8.1% to 7.7%.
  - A1C decreased by 2.3% for those with the highest A1Cs in the Control-IQ+ arm at the start of the study (≥9%).
- Time in range improved by 16% with Control-IQ+, resulting in 3.8 more hours/day in range (70-180 mg/dL) than baseline, and 3.4 more hours/day in range than the control group.
  - Time in range increased from 48% to 64% with Control-IQ+, and 51% to 52% for the control group. The treatment effect with Control-IQ+ was evident in the first week and sustained for the duration of the study.
  - Mean glucose, time >180 mg/dL, time >250 mg/dL, and the frequency of prolonged hyperglycemic events were all

lower with Control-IQ+ compared to the CGM only group.
    - Treatment effects of Control-IQ+ on time in range and mean glucose were evident during both daytime and nighttime hours.
- Insulin use decreased by 8 units/day in the Control-IQ+ group, compared to an increase of 2 units/day in the CGM group, representing a difference of -10 units/day in favor of Control-IQ+.
- Benefits of Control-IQ+ compared to the control group were evident across a broad range of baseline characteristics including sex, race/ethnicity, body mass index, income, education, and prior experience with diabetes technology.

Safety

- Use of Control-IQ+ proved safe, raising no new safety signals unique to type 2 diabetes users compared to previous type 1 diabetes studies.
    - The frequency of hypoglycemia was low in both groups. One severe hypoglycemic event occurred in the Control-IQ+ group, which was successfully treated with oral carbohydrates.
    - There were no DKA or hyperosmolar hyperglycemic syndrome events in the study.

Additional Data Highlights Presented at ATTD

Additional data related to bolus behavior and system usability/satisfaction were presented today during a symposium at the 18th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD).

Meal Bolusing Methods

Different bolusing strategies were permitted throughout the study, including use of a carbohydrate calculator or entering a set amount of carbohydrate or units of insulin for small, medium, and large meals. 75% of participants were not performing carbohydrate counting at enrollment.

- All bolus strategies were very effective with Control-IQ+, resulting in similar, significant reductions in A1C across groups
- Those who used fewer user-initiated boluses, receiving a high percent of their insulin through Control-IQ+ moderated insulin delivery, also did well.
- No increase in hypoglycemia was observed between bolusing methods

Usability and Satisfaction

- Patient reported outcomes related to device satisfaction and sleep quality improved significantly with Control-IQ+ compared to the CGM group at the end of the study.
- Control-IQ+ received high usability scores regardless of bolusing strategy

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ+ advanced hybrid closed-loop technology. Tandem Diabetes Care is based in San Diego, California. 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, the potential of Control-IQ+ to improve outcomes for people living with type 2 diabetes who use insulin, while helping alleviate daily therapy burden and improve quality of life. These forward-looking statements are subject to numerous risks and uncertainties, including risks, for example, that the real-world clinical benefits from use of Control-IQ+ technology may not match the results reported in the study and the level of customer satisfaction from the use of our products, as well as other risks identified in our most recent Annual Report on Form 10-K, 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.

Important Safety Information

RX ONLY. The t:slim X2 pump with interoperable technology (the pump) and Control-IQ+ technology (Control-IQ+) are intended for single patient use. The pump and Control-IQ+ are indicated for use with NovoLog or Humalog U-100 insulin. t:slim X2 insulin pump: The pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons 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 persons 2 years of age and greater. Control-IQ+ technology: Control-IQ+

technology is intended for use with compatible integrated continuous glucose monitors (iCGM, sold separately) and alternate controller enabled (ACE) pumps 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 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

WARNING: Control-IQ+ should not be used in anyone under the age of 2 years old with Type 1 diabetes or under the age of 18 years old with Type 2 diabetes. It should also not be used in patients who require less than a total daily insulin dose of 5 units of insulin per day or who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed in order for Control-IQ+ to operate safely.

Users of the pump and Control-IQ+ must: use the insulin pump, iCGM, and all other system components in accordance with their respective instructions for use. Failure to follow these instructions for use could result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250318304173/en/

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