Tandem Diabetes Care Announces FDA Clearance of Control-IQ+ Automated Insulin Delivery Technology for People with Type 2 Diabetes

February 25, 2025

SAN DIEGO--(BUSINESS WIRE)--Feb. 25, 2025-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM), a leading insulin delivery and diabetes technology company, today announced that its next-generation automated insulin delivery (AID) algorithm, Control-IQ+ technology (Control-IQ+), has been cleared by the United States Food and Drug Administration (FDA) for use by people with type 2 diabetes ages 18 and older. Control-IQ+, already cleared for use by people with type 1 diabetes, builds on the company's proven Control-IQ algorithm and includes enhancements to accommodate input of expanded weight and total daily insulin ranges. Control-IQ+ is expected to be available for new and existing customers in the United States in March 2025.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250225281388/en/

The t:slim X2 insulin pump with Control-IQ+ technology from Tandem Diabetes Care. (Photo: Business Wire)

"We have seen firsthand, through numerous clinical and real-world studies, how Control-IQ has improved health outcomes and quality of life for our users with type 1 diabetes," said John Sheridan, president and chief executive officer. "It is a natural evolution of our mission to bring the same AID technology that helped to make Tandem the #1 recommended insulin pump brand by both healthcare providers and people living with type 1 diabetes to adults with type 2."[1,2]

Control-IQ powers both Tandem insulin delivery systems – the t:slim X2 and Tandem Mobi – to provide proven, best-in-class outcomes. Results from major studies of Tandem's technology in type 1 diabetes, including those published by the *New England Journal of Medicine* (October 2019, August 2020, March 2023), show immediate and sustained glycemic improvements, including more time in range and improved sleep.[3]

This expanded label indication for type 2 diabetes is based on results from a recently completed pivotal trial, representing the first large-scale, randomized, controlled study of an automated insulin delivery system, completed in more than 300 people with type 2 diabetes. The trial compared use of a t:slim X2 pump with Control-IQ+ technology to a control group who continued their existing multiple daily injections regimens. Both groups used a Dexcom G6 Continuous Glucose Monitoring (CGM) System for the duration of the study. Full study results will be presented at the 18th International Conference on Advanced Technologies & Treatments for Diabetes taking place in Amsterdam, the Netherlands in March 2025.

"Type 2 diabetes affects millions of Americans and increases the risk of serious health conditions, including heart disease, stroke, kidney disease, and nerve damage, reinforcing the importance of consistent management of blood sugar," said Jordan Pinsker, MD, chief medical officer. "More than 2 million people in the U.S. rely on intensive insulin therapy to manage their type 2 diabetes, and we are proud to bring this life-changing technology to a group that has historically had limited options for diabetes management."

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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Follow Tandem Diabetes Care on Facebook at www.facebook.com/TandemDiabetes.
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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 anticipated timing for the U.S. availability of Control-IQ+, our ability to provide the software update for current Tandem pump users and Tandem pumps pre-loaded with the Control-IQ+ software, the anticipated timing of the presentation of full study results, and our mission to bring Control-IQ+ to persons with type 2 diabetes requiring intensive insulin. These forward-looking statements are subject to numerous risks and uncertainties, including the risks associated with our ability to develop, scale, and maintain systems, personnel and infrastructure to support the expansion of our products into the type 2 diabetes market segment 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 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.

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1 Seagrove Partners HCP Perspectives (Devices), September 2024 Insulin Delivery section N=269.

2 dQ&A US Diabetes Connections Patient Panel Report, Q1 2024 (Jan.-March 2024)

3 Breton MD, Kovatchev BP. One-year real-world use of the Control-IQ advanced hybrid closed-loop technology. Diabetes Technol Ther. 2021;23(9):601-608. doi: 10.1089/dia.2021.0097

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