Tandem Mobi, World's Smallest Durable Insulin Delivery System, Receives FDA Clearance

July 11, 2023

SAN DIEGO--(BUSINESS WIRE)--Jul. 11, 2023-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced U.S. Food and Drug Administration (FDA) clearance for the Tandem Mobi insulin pump for people with diabetes age 6 and up, expanding the company's portfolio of products. The Tandem Mobi is fully controllable from a mobile app and is the world's smallest durable automated insulin delivery system.[1]

"Testing the limits of pump miniaturization, Tandem Mobi joins the t:slim X2 pump in our family of insulin delivery solutions bringing new options in wearability, the flexibility to disconnect, and full phone control," said John Sheridan, president and chief executive officer. "Through this expansion, we are delivering on our commitment to bring greater choice, along with the proven benefits of Tandem's technology, to more people living with diabetes."

Key Tandem Mobi System Features:

The Tandem Mobi features a 200-unit insulin cartridge and an on-pump button that provides an alternative option to phone control for bolusing insulin. Additional features include:

- Multiple Wear Options – Less than half the size of the t:slim X2 pump, Tandem Mobi can fit in a coin pocket, be clipped to clothing, or worn on-body with an adhesive sleeve (sold separately).
- Detachable Infusion Sets – Compatible with all existing Tandem-branded infusion sets manufactured by the Convatec Group, including a new five-inch tubing option made just for Tandem Mobi. Infusion sets allow users to temporarily disconnect from their pump for convenience and provide the flexibility of more than 30 mix-and-match infusion site and tubing length combinations.
- AID Compatibility – Designed for use as part of an automated insulin delivery (AID) system, the Tandem Mobi features Control-IQ technology.
- Mobile App Control – Full iOS mobile control through a user's compatible iPhone
- Modern Technology – Inductive charging and capable of wireless remote software updates via a compatible smartphone

A limited release of Tandem Mobi is expected to start in late 2023 with full commercial availability planned in early 2024. To sign up for notifications, please visit tandemdiabetes.com/mobi.

About Control-IQ Advanced Hybrid Closed-Loop Technology

The Tandem Mobi will be offered with Control-IQ technology, a hybrid-closed loop algorithm for use by people with type 1 diabetes age 6 and up. Control-IQ technology uses compatible continuous glucose monitoring (CGM) sensor values to predict glucose levels 30 minutes ahead and adjust insulin delivery every 5 minutes to help prevent highs and lows, while still allowing the user to manually bolus for meals. It can also deliver automatic correction boluses (up to one an hour) to help prevent hyperglycemia.[2] Real-world data shows immediate and sustained glycemic improvements — including more time in range and better sleep.[3] Results from major studies of Control-IQ technology were published by the *New England Journal of Medicine* in October 2019, August 2020, and March 2023.

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, the anticipated timing for the limited release and subsequent commercial launch of the Tandem Mobi system. These forward-looking statements are subject to numerous risks and uncertainties, including risks associated with the commercial launch of a new product, as well as manufacturing risks and risks related to adequate reimbursement coverage. These and other risks are identified and described in greater detail under the "Risk Factors" heading of our most recent Annual Report on Form 10-K. 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.

Indications for Use

Tandem Mobi insulin pump: The Tandem Mobi insulin pump with interoperable technology (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 intended for single patient, home use and requires a prescription.
The pump is indicated for use in individuals six years of age and greater.

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 use. The pump is indicated for use with U-100 insulin only.

Control-IQ technology: Control-IQ technology is intended for use with a compatible 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.

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.

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 a Tandem insulin 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 Tandem 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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[1] As of July 2023. Data on file, Tandem Diabetes Care.

[2] If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 110 mg/dL and delivers 60% of that value. An Automatic Correction Bolus will not occur within 60 minutes of a bolus that has been delivered or cancelled.

[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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Media Contact:
858-255-6388
media@tandemdiabetes.com

Investor Contact:
858-366-6900
IR@tandemdiabetes.com

Source: Tandem Diabetes Care, Inc.