

Tandem Diabetes Care Announces FDA Designation of Basal-IQ Technology as an Interoperable Automated Glycemic Controller

March 2, 2020

SAN DIEGO--(BUSINESS WIRE)-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced U.S. Food and Drug Administration (FDA) clearance of its Basal-IQ™ technology as an interoperable automated glycemic controller (iAGC). This is the second system to receive iAGC designation by the FDA, following the Company's clearance of the t:slim X2™ insulin pump with Control-IQ™ technology in December 2019.

The FDA has classified three categories for the interoperability of devices as a complete automated insulin dosing (AID) system, which include an alternate controller-enabled insulin pump (ACE pump), an integrated continuous glucose monitor (iCGM) and an iAGC. The t:slim X2 insulin pump was also the first to receive an ACE infusion pump classification in February 2019, and the first insulin pump designated as compatible with iCGM devices in June 2018.

"Aligning Basal-IQ technology with Control-IQ technology under the FDA's new regulatory path helps streamline our internal processes and provides us with a consistent approach to making future product enhancements," said John Sheridan, president and chief executive officer. "Customer choice is a core tenet of our Company and this clearance supports our commitment to the interoperability of our AID technologies with our current and future insulin pump offerings."

About Basal-IQ Predictive Low Glucose Suspend Technology

The simple-to-use t:slim X2 insulin pump with Basal-IQ predictive low glucose suspend technology uses glucose values from an integrated Dexcom G6 continuous glucose monitor to predict and help prevent lows with zero fingersticks.^{1,2,3} Basal-IQ technology uses CGM values to help reduce the frequency and duration of low-glucose events by predicting glucose levels 30 minutes ahead and suspending insulin if they are expected to drop below 80 mg/dL or if a CGM reading falls below 70 mg/dL. Insulin delivery resumes as soon as sensor glucose values begin to rise.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience. The Company takes an innovative, user-centric approach to the design, development and commercialization of products for people with diabetes who use insulin. Tandem manufactures and sells the t:slim X2 insulin pump with Basal-IQ technology and the t:slim X2 insulin pump with Control-IQ technology. The t:slim X2 pump is capable of remote feature updates using a personal computer. Tandem is based in San Diego, California.

Important Safety Information:

Caution: Federal (USA) law restricts the t:slim X2 insulin pump and the t:slim X2 pump with Basal-IQ technology to sale by or on the order of a physician. The t:slim X2 pump and the t:slim X2 pump with Basal-IQ technology are intended for single patient use. The t:slim X2 pump and the t:slim X2 pump with Basal-IQ technology are indicated for use with NovoLog or Humalog U-100 insulin.

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 6 years of age and greater. **t:slim X2 insulin pump with Basal-IQ technology:** When used with a compatible integrated continuous glucose monitor (iCGM), the t:slim X2 insulin pump with Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. The t:slim X2 pump with Basal-IQ technology is indicated for use in individuals 6 years of age and greater.

The t:slim X2 pump with Basal-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Users of the t:slim X2 pump or the t:slim X2 pump with Basal-IQ technology must: be able and willing 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, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. For additional important safety information, visit tandemdiabetes.com/safetyinfo.

Tandem Diabetes Care and Basal-IQ are registered trademarks, and t:slim X2, Control-IQ and t:simulator are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. All other third-party marks are the property of their respective owners.

Forward Looking Statement

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, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements relate to, among other things, the Company's ability to streamline its internal processes, make future product enhancements and/or integrate its AID technologies with future ACE pump offerings. These statements are subject to numerous risks and uncertainties, including the potential that the Company may not be able to successfully improve its internal processes as a result of this clearance, make future product enhancements or develop future insulin pump systems, or that those systems may not be approved by the FDA in a timely manner or at all, as well as other risks identified in our most recent Annual Report on Form 10-K 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. 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.

¹ If glucose alerts and CGM readings do not match symptoms or expectations or if taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.

² Dexcom G6 CGM sold separately

³ The Dexcom G6 CGM transmitter can only be paired with one medical device (either a Dexcom receiver or t:slim X2 pump) and one consumer device (phone or tablet) at the same time.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200302005304/en/): <https://www.businesswire.com/news/home/20200302005304/en/>

Tandem Diabetes Care Contact Information:

Media: Steve Sabicer, 714-907-6264, ssabicer@thesabicergroup.com

Investors: Susan Morrison, 858-366-6900 x7005, IR@tandemdiabetes.com

Source: Tandem Diabetes Care, Inc.