

# Tandem Diabetes Care Announces Commercial Launch of t:slim X2 Insulin Pump with Basal-IQ Technology in the United States

August 17, 2018

SAN DIEGO--(BUSINESS WIRE)--Aug. 17, 2018-- Tandem Diabetes Care®, Inc. (NASDAQ: TNDM), a medical device company and manufacturer of the only touchscreen insulin pumps with continuous glucose monitoring (CGM) integration, today announced its launch of the t:slim X2<sup>TM</sup> Insulin Pump with Basal-IQ<sup>TM</sup> Technology, a predictive low glucose suspend (PLGS) feature designed to help reduce the frequency and duration of low glucose events (hypoglycemia). It is integrated with the Dexcom G6® CGM System, which requires no fingersticks for calibration or diabetes treatment decisions. The Company has begun sending emails with update instructions to all in-warranty t:slim X2 users in the United States, who have the option to add the new feature free of charge via remote software update. Pumps pre-loaded with Basal-IQ Technology are expected to begin shipping to new customers by the end of August.

Tandem's Basal-IQ algorithm is designed to look 30 minutes into the future to predict where glucose levels are heading. The device suspends insulin delivery when low glucose is predicted, then automatically resumes insulin delivery once glucose levels begin to rise. In the pivotal clinical study, use of the t:slim X2 Pump with Basal-IQ Technology demonstrated a 31 percent relative reduction in time spent below 70 mg/dL, with no rebound hyperglycemia compared to a CGM-enabled insulin pump without the feature. The system received high usability scores in the study, with 93 percent of participants indicating that the system was easy to use, and 97 percent indicating that they felt confident using the system.<sup>4</sup>

"This launch marks the achievement of our goal to offer people with diabetes a simple-to-use automated insulin delivery feature that can reduce time spent low without adding significant burden to the pump therapy experience," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "Our ability to provide remote software updates, allowing in-warranty t:slim X2 Pump users the ability to add Basal-IQ Technology to their current pumps using a personal computer, is unparalleled in the industry and further differentiates the t:slim X2 Insulin Pump from other devices on the market."

## Update Instructions for In-warranty t:slim X2 Pump Users

No action is required at this time. Individual emails are being sent to all in-warranty t:slim X2 Pump users in the United States with information on how to start the update process. Emails are being sent out in batches, with all users anticipated to have received the information by the end of August. The Basal-IQ feature update will require a new prescription and completion of a 45-minute online training module, all of which will be coordinated through a simple-to-use online portal. Internet and computer access are required for pump updates. Basal-IQ Technology is only compatible with the Dexcom G6® CGM System. t:slim X2 Pump users who have Dexcom G5® Mobile CGM supplies they plan to use may want to postpone this update until they are ready to switch to the new Dexcom G6 CGM System. More information about the update process and system requirements is available at <a href="https://www.tandemdiabetes.com/X2update">www.tandemdiabetes.com/X2update</a>.

### Free Basal-IQ Technology Demo App

Tandem's free t:simulator™ App lets users experience the touchscreen interface of the t:slim X2 Insulin Pump with Basal-IQ Technology directly on a mobile device. For more information and to download the app, visit <a href="http://www.tandemdiabetes.com/tsimulator">http://www.tandemdiabetes.com/tsimulator</a>.

#### 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. The t:slim X2 Pump is capable of remote feature updates using a personal computer and is the only automated insulin delivery device approved for children as young as 6 years old. Tandem is based in San Diego, California.

For additional product and safety information, or to begin the order process, visit <u>www.tandemdiabetes.com/tslimX2</u> or call 877-801-6901, Monday – Friday between 6am and 5pm Pacific Time.

## **Important Safety Information**

RX ONLY. The t:slim X2 Insulin Pump with Basal-IQ Technology (the System) consists of the t:slim X2 Insulin Pump, which contains Basal-IQ Technology, and a compatible CGM. CGM sold separately. The t:slim X2 Insulin 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 t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System. When the System is used with a compatible iCGM, the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings. Interpretation of the System results should be based on the trends and patterns seen with several sequential readings over time. CGM also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Compatible iCGM systems are intended for single patient use and require a prescription. The System is indicated for use in individuals 6 years of age and greater. The System is intended for single patient use and requires a prescription. The System is indicated for use with NovoLog or Humalog U-100 insulin. The System is not approved for use in pregnant women, persons on dialysis, or critically ill patients.

Tandem Diabetes Care is a registered trademark, and t:slim X2, Basal-IQ and t:simulator are trademarks of Tandem Diabetes Care, Inc.Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. All other trademarks 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 anticipated timing for the commercial launch of the t:slim X2 with Basal-IQ Technology and our ability to offer the Basal-IQ software update for current t:slim X2 Pump users. These statements are subject to numerous risks and uncertainties, including our ability to commence commercial scale manufacturing of the t:slim X2 with Basal-IQ Technology, our ability to launch a new system to facilitate online training and prescription handling for existing t:slim X2 customers upgrading their existing devices, and the risk that we may encounter other challenges that may delay the commercial launch of t:slim X2 with Basal-IQ Technology, 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. 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.

- <sup>1</sup> If glucose alerts and CGM readings do not match symptoms or expectations or if taking over the recommended maximum dosage amount of 1000 mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.
- <sup>2</sup> Dexcom G6 CGM sold separately. 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.
- <sup>3</sup> A new prescription and additional training are required for this software update.
- <sup>4</sup> Forlenza GP, Li Z, Buckingham BA, Pinsker JE, et al. Predictive low glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial [published online August 8, 2018]. Diabetes Care. doi:10.2337/dc18-0771.

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