



Tandem Diabetes Care Presents Positive Real-World Data from Pediatric Users of t:slim X2 Insulin Pump with Basal-IQ Technology at International Conference

October 30, 2019

SAN DIEGO--(BUSINESS WIRE)--Oct. 30, 2019-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced presentation of real-world data from pediatric users of the t:slim X2™ insulin pump with Basal-IQ® predictive low-glucose suspend technology at the 45th annual conference of the International Society for Pediatric and Adolescent Diabetes (ISPAD). Data from 2,696 users under the age of 18 years old showed an overall rate of hypoglycemia of only 0.9 percent when using Basal-IQ technology. A subgroup of users with at least 21 days of sensor-augmented pump data prior to use of Basal-IQ technology demonstrated a 31 percent reduction in hypoglycemia following introduction of the feature (n=491).

Data Highlights

The study included de-identified real-world data uploaded to Tandem's t:connect® web application between August 31, 2018 and March 14, 2019, which was retrospectively analyzed to assess hypoglycemia outcomes.

Overall Group (n=2,696) – The overall rate of hypoglycemia (defined as percent median time spent with sensor readings <70 mg/dL or 3.9 mmol/L) for this group was 0.9 percent. Algorithm-enabled insulin suspensions occurred on average 4.9 times per day for an average 15.5 minutes per suspension.

Subgroup (n=491) – Pre-post analysis demonstrated median time spent <70 mg/dL or 3.9 mmol/L decreased from 1.6 to 1.1 percent upon introduction of Basal-IQ technology (p = <0.001), representing a 31 percent reduction in hypoglycemia. Sensor time-in-range (defined as 70-180 mg/dL or 3.9-10.0 mmol/L) remained steady between pre- and post-Basal-IQ technology use, however, there was a significant decrease in sensor glucose values greater than 300 mg/dL or 16.7 mmol/L (p=0.007).

About the t:slim X2 Insulin Pump with Basal-IQ 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*. The t:slim X2 insulin pump includes advanced features like a large color touchscreen, rechargeable battery, Bluetooth® wireless technology, USB connectivity and watertight construction (IPX7)¹. It is capable of remote software updates using a personal computer, offering the potential for in-warranty users to access new features as they meet necessary regulatory requirements². The t:slim X2 insulin pump is up to 38 percent smaller than other insulin pumps and holds up to 300 units of insulin.³

Launch of the t:slim X2 insulin pump with Basal-IQ technology has begun in select international geographies. It is currently available on new t:slim X2 insulin pumps and as a software update to all in-warranty t:slim X2 insulin pump users in the United Kingdom, Sweden, Denmark, Spain, Italy, the Czech Republic, and South Africa.

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's flagship product, the t:slim X2 insulin pump, is capable of remote software updates using a personal computer and features integrated continuous glucose monitoring. Tandem is based in San Diego, California.

Tandem Diabetes Care, t:connect, and Basal-IQ are registered trademarks, and t:slim X2 is a trademark of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. The Bluetooth wordmark is a registered trademark owned by Bluetooth SIG, Inc. and any use of such mark by Tandem Diabetes Care, Inc. is under license. All other third-party marks are the property of their respective owners.

Important Safety Information for the t:slim X2 Insulin Pump with Basal-IQ Technology

Federal (USA) law restricts this device to sale by or on the order of a physician. 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, Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. 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/NovoRapid or Humalog U-100 insulin. The System is not approved for use in pregnant women, persons on dialysis, or critically ill patients. The pump is not intended for anyone unable or unwilling 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 their healthcare provider regularly. The user must also have adequate vision and/or hearing to recognize all functions of the pump, including alerts. For detailed indications for use and safety information, visit tandemdiabetes.com/safetyinfo.

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 ability of the t:slim X2 pump to provide remote feature updates, the timing and outcome of regulatory approvals for new product features and updates, and the ability of our products to improve customer satisfaction and clinical outcomes. These statements are subject to numerous risks and uncertainties, including the risks that technical problems may prevent or delay remote software updates, regulatory agencies may fail to approve new product features or updates on our expected timeframe or at all, and the level of customer satisfaction from the use of our products and features may be different from what we expect, as well as other risks identified in Tandem’s most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively, 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. 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.

* If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. Dexcom G6 CGM sold separately.

¹ Tested to a depth of 3 feet for 30 minutes

² Additional feature updates are not currently available for the t:slim X2 insulin pump with Basal-IQ technology and are subject to future FDA approvals. A prescription and additional training may be required to access certain future software updates.

³ 38 percent smaller than MiniMed 630G and 670G and at least 28 percent smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20191030005928/en/>

Source: Tandem Diabetes Care, Inc.

Tandem Diabetes Care Contact Information:

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

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