TANDEM INVESTOR CENTER

Tandem Diabetes Care Announces Publication of PROLOG Study Results in Diabetes Care Journal

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Study Demonstrates Significant Reduction in Hypoglycemia without Rebound Hyperglycemia

SAN DIEGO--(BUSINESS WIRE)--Aug. 8, 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 the online publication of results from the PROLOG (PLGS for Reduction of Low Glucose) study of the t:slim X2™ Insulin Pump with Basal-IQ™ predictive low glucose suspend technology ir the medical journal *Diabetes Care*. The study demonstrated that the t:slim X2 Pump with Basal-IQ Technology significantly reduced hypoglycemia without rebound hyperglycemia, compared to time on a t:slim X2 Pump with integrated CGM and no automated insulin suspension. No severe adverse events were observed in the study during use of the Basal-IQ feature.

“The results seen in the PROLOG study demonstrate that an automated insulin delivery system can have a significant impact on glycemic control without being overly complicated or burdensome for the patient,” said Dr. Greg Forlenza, principal investigator for the Barbara Davis Center for Diabetes at the University of Colorado School of Medicine. “We think the t:slim X2 Insulin Pump with Basal-IQ Technology will be a welcome addition for healthcare providers and clinics looking for a simple-to-teach system that can help reduce the risk of hypoglycemia without significantly increasing the training and support demands on their practice.”

Basal-IQ Technology uses CGM readings to predict glucose levels 30 minutes ahead. If the glucose level is predicted to be less than 80 mg/dL, or if a CGM reading falls below 70 mg/dL, insulin delivery is suspended. Insulin delivery resumes as soon as sensor glucose values begin to rise.

“Subjects in the PROLOG study adopted the Basal-IQ system quickly and easily. There was also no evidence of alarm fatigue, since alerts related to insulin suspension and resumption are optional, allowing the feature to operate quietly in the background,” said Dr. Jordan Pinsker, senior research physician at Sansum Diabetes Research Institute in Santa Barbara, California. “The high usability scores are remarkable and match the level of positive user experience feedback we received from participants over the course of the study.”

Results from this study supported a regulatory filing for the t:slim X2 Pump with Basal-IQ Technology to the U.S. Food and Drug Administration (FDA). The study was conducted using Dexcom G5® Mobile CGM technology, but the system was also designated by the FDA as compatible with integrated CGM (iCGM) devices at the time of approval in June 2018. The Company is planning for commercial launch of the Basal-IQ feature in August 2018 with Dexcom G6® CGM integration, the first FDA-approved iCGM device, which requires no fingersticks for calibrations or mealtime dosing and allows users to share data with up to five followers.*

Summary of Data Published in Diabetes Care[1]

Reductions in hypoglycemia – Use of the t:slim X2 Pump with Basal-IQ Technology in the PROLOG study reduced the number of sensor glucose readings below 70 mg/dL by 31 percent compared to the control period without automated insulin suspension. The reduction of time spent in low glucose was accomplished without any increase in the rate of hyperglycemia. Participants with higher hypoglycemia entering the study saw the largest improvement. A significant hypoglycemia reduction was seen with Basal-IQ Technology in all groups, irrespective of age, baseline HbA1c, or baseline hypoglycemia rates.

Usability – The t:slim X2 Pump with Basal-IQ Technology scored very high on the System Usability Scale survey, a standardized 10-item questionnaire that measures the perceived usability of a system, often used to evaluate non-medical consumer electronics. 93 percent of participants thought the system was easy to use, and 97 percent indicated they felt confident using the system.

Study adherence – Overall study adherence was high, with 99 percent of those enrolled completing the trial, and with the system active for 95 percent of the time during the Basal-IQ period. Median CGM use during the study periods was 95 percent when using Basal-IQ and 94 percent when using the pump without automated insulin suspension.

Insulin suspensions and insulin use – The mean suspension duration was 18 minutes per event, with a mean pump suspension time of 104 minutes per day. Mean daily bolus insulin amounts were identical between study phases. The basal insulin dose was reduced by approximately four percent in the Basal-IQ phase compared with the control period without automated insulin suspension. Mean basal insulin delivery was 1.2 units per day lower when using the Basal-IQ feature ($P < 0.001$).

Safety/adverse events – No severe hypoglycemic events were observed in the Basal-IQ phase of the study. There was one severe hypoglycemic event in the study phase without automated insulin suspension. There was no significant difference in the appearance of ketones between the two treatment phases.

The PROLOG study was a multi-center, randomized, crossover clinical trial comparing two three-week periods of at-home insulin pump use, one period using the t:slim X2 Pump with Basal-IQ Technology, and another period using a CGM-integrated t:slim X2 Pump without automated insulin suspension. The study included 102 participants with type 1 diabetes ages 6 to 72 at four research centers across the United States and was coordinated by the Jaeb Center for Health Research in Tampa, Florida.

t:slim X2 Insulin Pump with Basal-IQ Technology Coming Soon

The t:slim X2 Insulin Pump with Basal-IQ Technology can be ordered today and is anticipated to begin shipping in August 2018. For additional product and safety information, or to begin the order process, visit www.tandemdiabetes.com/tslimX2, or call (877) 801-6901, Monday – Friday between 6:00am and 5:00pm Pacific Time.

Free Software Update for Current t:slim X2 Pump Users

All in-warranty t:slim X2 Pump users in the United States have the option to add the Basal-IQ feature free of charge via a software update using a personal computer. Expected to release in August 2018, the Basal-IQ feature update will require a new prescription and completion of a 45-minute online training module. Internet and computer access are required for pump updates. Information about the requirements and update process is available at www.tandemdiabetes.com/X2update.

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 http://www.tandemdiabetes.com/tsimulator.

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. Tandem 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 first insulin pump designated as compatible with integrated continuous glucose monitoring (iCGM) devices. Tandem is based in San Diego, California.

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 launch of the t:slim X2 Insulin Pump with Basal-IQ Technology in August 2018 and the ability to provide the Basal-IQ feature update to existing t:slim X2 users via a software update. These statements are subject to numerous risks and uncertainties, including the risk that Tandem may encounter other challenges that may delay the commercial launch of the t:slim X2 Pump with Basal-IQ Technology or the company's ability to deliver software updates to existing t:slim X2 users, 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 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.

* 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. Separate Follow App required.

Reference:

1. 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. Diabetes Care. 2018 [In Press].

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Tandem Diabetes Care Contact Information:
Media:
Steve Sabicer, (714) 907-6264
ssabicer@thesabicergroup.com
or
Investors:
Susan Morrison, (858) 366-6900 x7005
smorrison@tandemdiabetes.com