August 15, 2017

Tandem Diabetes Care Begins Enrollment in Pivotal Trial for First Touchscreen Insulin Pump with Predictive Low Glucose Suspend (PLGS)

SAN DIEGO--(BUSINESS WIRE)-- Tandem Diabetes Care®, Inc. (NASDAQ: TNDM), a medical device company and manufacturer of the only touchscreen insulin pumps available in the United States, today announced enrollment of the first patients in an at-home pivotal trial for its t:slim X2™ Insulin Pump using Tandem's predictive low glucose suspend (PLGS) technology. The insulin pump system, which uses an integrated Dexcom G5® Mobile Continuous Glucose Monitor (CGM), is designed to suspend insulin delivery when low blood glucose is predicted and subsequently resume insulin delivery when glucose levels begin to rise.

The PROLOG (PLGS for Reduction Of LOw Glucose) study is a multi-center, randomized crossover study comparing two 3-week periods of at-home insulin pump use, one period using the t:slim X2 Pump with PLGS, and another period using a standard CGM-integrated t:slim X2 Pump without automated insulin suspension. The clinical trial will include 90 participants with type 1 diabetes ages 6 and above at five research centers across the United States and is being coordinated by the Jaeb Center for Health Research in Tampa, Florida. The primary endpoint of the study is to demonstrate a reduction in the percentage of CGM values below 70 mg/dL when using Tandem's PLGS algorithm.

"The start of this pivotal trial is another important step forward in our automated insulin delivery programs, and comes on the heels of very encouraging feasibility study data," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "We remain on track to submit our t:slim X2 Pump with predictive low glucose suspend to the FDA in early 2018. Subject to FDA approval, we are preparing to launch in summer of 2018, and plan to make this new feature accessible for existing t:slim X2 customers via a remote software update using our Tandem Device Updater."

"Mild to moderate hypoglycemia occurs frequently during the day for people with type 1 diabetes, but of more concern is the severe hypoglycemia which can occur at night causing seizures or even death. This is a real concern to all people living with type 1 diabetes, and especially parents of children with type 1," said Dr. Bruce Buckingham, Professor of Pediatric Endocrinology at The Lucille Salter Packard Children's Hospital, Stanford University, and principal investigator of the PROLOG trial. "This new PLGS algorithm will allow for the automatic suspension of insulin delivery when glucose is predicted to be low. This is beneficial throughout the day but can be lifesaving at night when a person is otherwise unable to react."

Full trial details and site contact information can be found at https://clinicaltrials.gov/ct2/show/NCT03195140.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company with an innovative, user-centric and integrated approach to the design, development and commercialization of products for people with diabetes who use insulin. The Company manufactures and sells the t:slim X2™ Insulin Pump, the slimmest and smallest durable insulin pump currently on the market; the t:flex® Insulin Pump, the first pump designed for people with greater insulin requirements; and the t:slim G4™ Insulin Pump, the first continuous glucose monitoring-enabled pump with touchscreen simplicity. Tandem is based in San Diego, California.

About the Tandem Device Updater

The Tandem Device Updater is a Mac® and PC-compatible application for the remote update of Tandem insulin pump software. Remote software updates have the potential to allow all t:slim X2 Pump users access to future features as they are approved by the FDA. Tandem is the only company that allows its customers to remotely update features on their insulin pump from home using a personal computer without waiting for their insurance to cover a new device.[1] Subject to FDA approval, Tandem plans to make the new PLGS feature available to existing t:slim X2 customers via a remote software update using the Tandem Device Updater.[2]

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #tslimX2, #tslimG4, #tflex, #tconnect, and $TNDM.

Follow Tandem Diabetes Care on Facebook at www.facebook.com/TandemDiabetes.

Follow Tandem Diabetes Care on LinkedIn at https://www.linkedin.com/company/tandemdiabetes.

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 include statements regarding the Company's ability to successfully complete the pivotal trial for the t:slim X2 Pump with PLGS when anticipated, submit future regulatory applications, secure regulatory approvals for the t:slim X2 Pump with PLGS, and offer future software improvements and enhancements to Tandem pumps using the Tandem Device Updater. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, successful completion of the pivotal trial is dependent on the rate of enrollment in the study and the cooperation of multiple clinical research sites that are largely outside of the Company's control. In addition, the pivotal trial results may not be adequate to support a future regulatory application when anticipated and it is possible that the t:slim X2 Pump with PLGS may not be approved by the FDA in a timely manner or at all. Further, the future commercialization of the Company's products may be negatively impacted by many other factors, including: lack of market acceptance by physicians, payors and people with diabetes; the potential that newer products that compete with the Company's products, or other technological breakthroughs for the monitoring, treatment or prevention of diabetes, may render the Company's products obsolete or less desirable; and the potential that the Tandem Device Updater may fail to perform according to its specifications or may not provide people with diabetes with anticipated benefits. Other risks and uncertainties are identified in the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, and other documents that the Company files with the Securities and Exchange Commission. Investors 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] Available software updates for Tandem products can be found at www.tandemdiabetes.com/updater. Additional software updates and new features are subject to future FDA approvals. Charges may apply.

[2] Subject to FDA submission and approval. Charges may apply.

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