Tandem Diabetes Care Announces Plan to Use Remote Software Update Tool in Ongoing Clinical Trial

March 6, 2019

SAN DIEGO--(BUSINESS WIRE)--Mar. 6, 2019-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced that it intends to use its remote software update tool, the Tandem Device Updater, to resolve a Control-IQ technology software anomaly identified during the ongoing DCLP3 phase of the International Diabetes Closed Loop (IDCL) clinical trial. The Company anticipates that the software update will be available to study sites before the end of March.

“A primary reason for a larger pivotal clinical trial is to identify and resolve infrequent anomalies like this that may not appear in smaller studies. Being able to address this now helps us to offer a more robust product for our customers at launch,” said John Sheridan, president and chief executive officer. “Our ability to quickly develop and provide trial participants a remote software update is another example of the revolutionary power of our Tandem Device Updater, and our Company’s nimble research and development capabilities. We continue to prepare for the launch of our Control-IQ technology in the second half of this year, subject to successful completion of the study and FDA review.”

The anomaly relates to how the t:slim X2 insulin pump with Control-IQ technology handles continuous glucose monitoring (CGM) data under specific conditions, which could then impact the system’s prediction of future blood glucose values and automated insulin delivery. Manifestations of this anomaly are rare and have not resulted in any reportable adverse events; however, due to an increased risk of hypoglycemia, use of the Control-IQ software feature in the IDCL study will be temporarily suspended until the software update is available.

The Company is currently in discussions with the IDCL study investigators to evaluate any impact of the software update to the clinical or regulatory strategy for the t:slim X2 insulin pump with Control-IQ technology. Currently, approximately 120 out of 168 trial participants have completed the 6-month DCLP3 study. Individuals who complete the 6-month study period are then enrolled in a 3-month extension to the primary study. The Company has notified other clinical trial sponsors using Control-IQ technology of the anomaly and that a software update will be made available. The DCLP5 study, which is the pediatric arm of the IDCL study, will commence following availability of the updated software.

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.

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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 plan to use the Tandem Device Updater to resolve the Control-IQ technology software anomaly during an ongoing clinical trial, including the Company’s ability to resolve the software anomaly and the timing of the anticipated software update; whether the data from the IDCL trial will be adequate to support a future regulatory filing; the Company’s ability to obtain regulatory approval for the t:slim X2 with Control-IQ technology, and the timing of the anticipated commercial launch of the t:slim X2 with Control-IQ technology. These statements are subject to numerous risks and uncertainties, including: the Company may be unable to develop and deploy the software update when anticipated or at all; the FDA may not agree with the plan to temporarily suspend and then resume the use of Control-IQ technology as part of the DCLP3 study; the results of the Company’s ongoing clinical studies may not demonstrate the safety and effectiveness of the Company’s products under development or be sufficient to support a future regulatory filing; the Company may not be able to commence the DCLP5 study in a pediatric population when anticipated; as well as the other risks and uncertainties identified in the Company’s most recent Annual Report on Form 10-K and its other filings 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. The Company undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

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