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## **Tandem Diabetes Care Reports Successful Completion of First Pilot Study Using t:slim X2 Insulin Pump with TypeZero Hybrid Closed Loop Technology and Dexcom G6 Integration; Confirms IDCL Multi-site Study Timeline**

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 reported the successful completion of the first pilot study using a hybrid closed loop system featuring its t:slim X2™ Insulin Pump with embedded algorithms from TypeZero Technologies and integration with Dexcom® G6 Continuous Glucose Monitoring (CGM). This pilot study was the first of three in the National Institute of Health (NIH)-funded International Diabetes Closed Loop (IDCL) Trial using the t:slim X2 Pump running the algorithm directly on the pump. The second study is now moving forward with enrollment at seven clinical sites and is anticipated to begin in the first quarter of 2018. The IDCL Trial is expected to conclude with a pivotal study in 2018, and Tandem plans to use this data in a PMA submission to the U.S. Food and Drug Administration.

The hybrid closed loop system predicts high and low blood sugar levels and adjusts insulin delivery accordingly throughout the day, while still allowing the user to manually bolus for meals. In addition to basal insulin adjustments, the system also automates correction boluses. The hybrid closed loop software developed by TypeZero includes a series of algorithms developed from initial research conducted at the University of Virginia. To date, this technology has been used in more than 30 clinical studies involving more than 450 participants, with data referenced in a number of journal articles.<sup>1</sup>

"The first successful use of the commercial version of our hybrid closed loop system is a huge step forward, and the speed of the development cycle for this product has been impressive for our industry," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "We look forward to starting the pivotal study later this year and continue to prepare for a launch in the first half of 2019, subject to FDA approval."

"We have enjoyed introducing patients to this latest advancement in technology, featuring an easy-to-use system and an algorithm with a successful track record in past clinical trials of improving blood glucose control while simultaneously decreasing hypoglycemia," said Sue Brown, Associate Professor at the Center for Diabetes Technology at the University of Virginia and the endocrinologist in charge of the IDCL trials using this embedded technology. "This study was an exciting step forward in closed-loop technology for people with diabetes."

"Sensor accuracy is a critical component for automated insulin delivery, and we are excited to have the first integration of Dexcom's next-generation G6 CGM technology in this hybrid closed loop system," said Steve Pacelli, Executive Vice President of Strategy and Corporate Development at Dexcom. "We are proud to partner with Tandem in the IDCL trial and are thrilled to see this integrated product moving forward into multi-center studies."

The IDCL Trial started in late 2016 and is expected to include up to 360 adults with type 1 diabetes across all of its studies. Earlier phases of the IDCL used a Tandem insulin pump and Dexcom G5 sensor as part of a blood glucose control system that combined these devices with a smartphone running TypeZero's inControl closed loop algorithms. The latest series of studies, now using the fully-integrated system, began with the supervised 36 to 48-hour pilot study in 5 subjects conducted at the University of Virginia. The next study, scheduled to take place in early 2018, will be a two-week, at-home study with enrollment at seven centers across the United States. A pivotal trial is planned to take place at these same centers following successful completion and review of the two-week study.

### **About Tandem Diabetes Care, Inc.**

Tandem Diabetes Care, Inc. ([www.tandemdiabetes.com](http://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, the only pump capable of remote feature updates using a personal computer, now available with Dexcom G5® Mobile CGM integration, and the t:flex® Insulin Pump, the first pump designed for people with greater insulin requirements. Tandem is based in San Diego, California.

Tandem Diabetes Care and t:flex are registered trademarks, and t:slim X2 is a trademark of Tandem Diabetes Care, Inc. Dexcom, Dexcom G5 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 timing of anticipated enrollment, commencement and completion of the remaining studies that comprise the IDCL trial, whether the data from the IDCL trial will be adequate to support a future regulatory filing by Tandem and the anticipated launch of an integrated product in the first half of 2019. These statements are subject to numerous risks and uncertainties, including the risk that each of the remaining studies that comprise the IDCL trial will be completed as currently contemplated, Dexcom's ability to secure regulatory approval for the Dexcom G6 CGM, and Tandem's ability to rely on the data from the IDCL trial to support a future regulatory filing, 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. The companies undertake 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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<sup>1</sup> Recent Publications Highlighting Research Using TypeZero AP Technology: (a) Ly T, Buckingham B, DeSalvo et al. Day-and-Night Closed-Loop Control Using the Unified Safety System in Adolescents With Type 1 Diabetes at Camp. *Diabetes Care* 2016 Aug; 39(8): e106-e107. (b) Anderson S, Raghinaru D, Pinsky J, et al. Multinational Home Use of Closed-Loop Control Is Safe and Effective. *Diabetes Care*. 2016 Jul;39(7):1143-50. (c) Boris P. Kovatchev, Eric Renard, Claudio Cobelli, et al. Safety of Outpatient Closed-Loop Control: First Randomized Crossover Trials of a Wearable Artificial Pancreas. *Diabetes Care*. 2014 Jul; 37(7): 1789-1796.

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