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NIH-funded International Diabetes Closed Loop (IDCL) Trial to Combine Technologies from Tandem Diabetes Care, Dexcom and TypeZero

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, Dexcom, Inc. (NASDAQ: DXCM), a leader in continuous glucose monitoring (CGM) for people with diabetes, and TypeZero Technologies, LLC, a digital health and personalized medicine company, today announced that they are working together on the integration of their technologies into the NIH-funded International Diabetes Closed Loop (IDCL) Trial starting later this year.

This Smart News Release features multimedia. View the full release here:
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A Tandem insulin pump and Dexcom G5 sensor will be included as part of a blood glucose control system that combines these devices with a smartphone running TypeZero's inControl closed loop algorithm. The 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, TypeZero's inControl system also automates correction boluses. Tandem and Dexcom anticipate adding a Dexcom G6 sensor-integrated t:slim X2 Pump that incorporates inControl's algorithms directly into the pump's touchscreen interface to the IDCL Trial in 2017. The companies anticipate that the integrated design, together with data from the IDCL Trial, will be the basis for a future regulatory submission by Tandem.

"The IDCL Trial is designed as a pivotal trial of a closed-loop control-to-range system, and includes seven institutions in the U.S. and three in Europe led by the University of Virginia," said Boris Kovatchev, PhD, Director of the Center for Diabetes Technology at the University of Virginia and principal investigator of the IDCL Trial. "The integration of technology provided by Tandem, Dexcom, and TypeZero in this trial represents a new level of sophistication in artificial pancreas research and development."

"A world-class automated insulin delivery system needs to be simple to use, rely on the most accurate CGM data available, and use a proven and trusted algorithm," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "We believe the combination of Tandem, Dexcom, and TypeZero technologies will deliver all three, and we are honored to be working together with them for this trial."

"Our efforts with Tandem began with the display of CGM data on their t:slim G4 Pump and we are pleased to take this next step in the integration of our future products to support automated insulin delivery," said Steve Pacelli, EVP, Strategy & Corporate Development at Dexcom.

"The addition of Tandem's innovative touchscreen pumps to the IDCL Trial is tremendous, and a great first step in their integration of our inControl algorithm into a future software update for the t:slim X2 Pump," said Chad Rogers, Chief Executive Officer at TypeZero Technologies. "We look forward to bringing these solutions to patients in the upcoming IDCL trial and ultimately delivering a best-in-class automated insulin delivery solution to patients across the globe."

The IDCL Trial is expected to enroll 240 adults with type 1 diabetes and is projected to start in late 2016. TypeZero's technology 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 28 clinical studies including more than 475 participants, with data referenced in a number of journal articles.[1]

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 touch-screen simplicity. Tandem is based in San Diego, California.

About Dexcom, Inc.

Dexcom, Inc., headquartered in San Diego, CA, is dedicated to helping people better manage their diabetes by developing and marketing continuous glucose monitoring (CGM) products and tools for adult and pediatric patients. With exceptional performance, patient comfort and lifestyle flexibility at the heart of its technology, users have consistently ranked Dexcom highest in customer satisfaction and loyalty. For more information on the Dexcom CGM, visit www.dexcom.com.

About TypeZero Technologies, LLC

The world leader in clinically tested artificial pancreas solutions, TypeZero Technologies is a digital health and personalized medicine startup dedicated to revolutionizing the treatment and management of diabetes. TypeZero is combining next-generation data science techniques, proven metabolic models, and modern engineering practices to develop customized analytics tools and blood glucose control solutions to help people with diabetes improve their health and lives. TypeZero's current products include a smartphone-based Artificial Pancreas system, therapy optimization tools for health care providers, and advisory applications for smart insulin pens. To learn more, visit www.typezero.com.

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 and commencement of the IDCL trial, the use of a Tandem insulin pump and Dexcom G5 sensor as part of a system that combines these devices with a smartphone running TypeZero's inControl algorithm in the IDCL trial, the current plan to develop and use a Dexcom G6 sensor-integrated t:slim X2 Pump that incorporates the inControl algorithm directly into the pump's touchscreen interface as part of the IDCL trial in the future and whether the integrated design will be the basis for a future regulatory filing by Tandem. These statements are subject to numerous risks and uncertainties, including the risk that the IDCL trial will be completed as currently contemplated, Tandem's ability to complete the development of a Dexcom G6 sensor-integrated t:slim X2 that incorporates the inControl algorithm directly into the pump's touchscreen interface, 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 future regulatory filing, as well as other risks identified in Tandem's or Dexcom's most recent Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, respectively, and other documents that they 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.

[1] 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, Pinsker 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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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
or
Dexcom Contact Information:
Media:
Caren Begun, 856-424-2023
caren@greenroom.com
or
Investors:

Steven Pacelli, 858-200-0200
spacelli@dexcom.com
or
TypeZero Technologies Contact Information:
Media:
Meagan Collins, 434-284-8919
mcollins@typezero.com
or
Investors:
Chad Rogers, 434-284-8919
rogers@typezero.com

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