TANDEM INVESTOR CENTER

t:slim X2 Insulin Pump First to Receive New ACE Pump Classification by FDA

February 14, 2019

SAN DIEGO--(BUSINESS WIRE)--Feb. 14, 2019-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced that the U.S. Food and Drug Administration (FDA) has classified the t:slim X2™ insulin pump as the first in a new device category called Alternate Controller Enabled Infusion Pumps (ACE pumps). Along with this authorization, the FDA is establishing criteria, called special controls, which outline requirements for assuring the accuracy, reliability, cybersecurity and clinical relevance of ACE pumps, as well as describe the type of studies and data required to demonstrate acceptable pump performance. The approved indication for the t:slim X2 pump states that the pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

“This new classification of the t:slim X2 pump provides more flexibility for us as we make improvements to current products, create new products, and collaborate with best-in-class companies in the development of future automated insulin delivery systems,” said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. “This further establishes the role Tandem Diabetes Care has taken as a key innovator in the insulin pump industry, having launched the first touchscreen pump in the United States, the first pump capable of remote feature updates, the first pump approved as iCGM compatible, and now the first in this new interoperable pump category.”

“The FDA’s special controls set a new standard in our industry and define another component of the regulatory process for future automated insulin delivery systems,” said John Sheridan, executive vice president and COO of Tandem Diabetes Care. “Having the t:slim X2 pump approved with this new designation, combined with its ability for remote software updates, will enable more efficient and predictable development of new systems with current and future technology partners, and allow faster delivery of new innovations to our customers.”

About the t:slim X2 Insulin Pump

The simple-to-use t:slim X2 insulin pump includes advanced features like a large color touchscreen, rechargeable battery, *Bluetooth*® wireless technology, USB connectivity and watertight construction (IPX7)[1]. It is capable of remote software updates using a personal computer, offering the potential for users to access new features as they meet necessary regulatory requirements.[2] The t:slim X2 Pump is up to 38 percent smaller than other insulin pumps and holds up to 300 units of insulin.[3]

About ACE Pumps

According to the FDA, ACE pumps are devices intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with compatible external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

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.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes, use #tslimX2 and $TNDM.
Follow Tandem Diabetes Care on Facebook at www.facebook.com/TandemDiabetes.
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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 anticipated future growth of the Company; the expectation that this new classification provides the Company with more flexibility in the product development process generally; the potential that the Company will enter into additional third-party collaborations; and that this new classification will result in more efficient and predictable development of new systems. These statements are subject to numerous risks and uncertainties, including: the Company’s ability to continue to meet the special controls associated with ACE pumps; the Company’s ability to complete the development of future products, including the successful completion of current and planned clinical studies; that the results of clinical studies will support future regulatory submissions of new products; market acceptance of the Company’s existing products and products under development by physicians and people with diabetes; the Company’s ability to meet increasing operational and infrastructure requirements from higher customer interest and a larger base of existing customers; as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, 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.

[1] Tested to a depth of 3 feet for 30 minutes

[2] Future algorithms and integrations with compatible devices may not be developed, and would be subject to applicable regulatory requirements. A prescription and additional training may be required to access certain future software updates. Charges may apply.

[3] 38 percent smaller than MiniMed 630G and 670G and at least 28 percent smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.

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Source: Tandem Diabetes Care, Inc.

Media Contact:
Steve Sabicer
714-907-6264
ssabicer@thesabicergroup.com

Investor Contact:
Susan Morrison
858-366-6900 x7005
IR@tandemdiabetes.com