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# Tandem Diabetes Care Announces FDA Approval and Launch of t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM Integration

- Software Update Available for Current t:slim X2 Pump Users Via Personal Computer -

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 U.S. Food and Drug Administration (FDA) approval and commercial launch of the t:slim X2<sup>™</sup> Insulin Pump with Dexcom G5® Mobile continuous glucose monitoring (CGM) integration, the first sensor-augmented insulin pump approved to let users make treatment

decisions without pricking their finger<sup>1</sup>. The software featured on this pump will also be available to current t:slim X2 Pump users at no cost via remote software update, allowing them to add CGM integration to their existing pumps from home using a personal computer. Individual emails are being sent directly to t:slim X2 Pump customers with instructions on how to perform the update. The t:slim X2 Pump with Dexcom G5 Mobile CGM integration is approved for ages 6 and older.

This approval marks the Company's fifth new insulin pump launch in only 5 years and the second featuring Dexcom technology. It is the only available pump that conveniently displays a user's insulin delivery activity and Dexcom G5 Mobile CGM data together on a single device. The t:slim X2 Pump is also the only insulin pump capable of remote software updates<sup>2</sup>, allowing existing users to add features like CGM integration from home. It is up to 38% smaller than other pumps<sup>3</sup>, but includes advanced features like a large color touchscreen, Bluetooth® radio, rechargeable battery, USB connectivity, 300-unit insulin capacity and watertight construction (IPX7)<sup>4</sup>.

"We are setting a new standard in our industry by simultaneously offering our existing and future customers the benefits of best-in-class CGM integration on our simple-to-use touchscreen insulin pump," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "The t:slim X2 Pump is designed to accelerate the pace in which we can bring new innovations to people with diabetes, which is of particular importance as we develop software updates to add automated insulin delivery algorithms to our platform."

"Dexcom has been moving its technology forward at a rapid pace, and Tandem's ability to roll out remote software updates like this opens up exciting possibilities for faster integrations of our future products," said Steve Pacelli, Executive Vice President of Strategy and Corporate Development at Dexcom. "We are excited to have our latest CGM technology integrated with their t:slim X2 Insulin Pump, and to see it offered not only to new customers but also to existing t:slim X2 Pump users."

The t:slim X2 Pump can operate as a stand-alone insulin pump without CGM, or be paired with the Dexcom G5 Mobile CGM to track glucose continuously and display that information directly on the pump's home screen. Dexcom G5 Mobile is the only CGM system FDA approved to let users make treatment decisions without pricking their finger. Dexcom is also

consistently rated the #1 CGM brand in independent patient surveys<sup>5</sup>. In addition to integration with the t:slim X2 Pump, dynamic glucose data from the Dexcom G5 Mobile CGM can be easily accessed and shared using a compatible mobile device.

#### For additional t:slim X2 Pump product and safety information, or to begin the order process, visit <u>www.tandemdiabetes.com/tslimX2</u> or call 877-801-6901, Monday - Friday between 6am and 5pm Pacific Time

Download Tandem's free t:simulator<sup>™</sup> App to experience the touchscreen interface of the t:slim X2 Pump with Dexcom G5 Mobile CGM integration directly on your mobile device. For more information and to download the app, visit <u>http://www.tandemdiabetes.com/tsimulator</u>.

# Information for Current t:slim X2 Pump Users

All eligible t:slim X2 Pump users have the option to add Dexcom G5 Mobile CGM integration via a software update using a personal computer. Individual emails are being sent directly to t:slim X2 Pump customers with instructions on how to perform the update. The software update is Mac® and PC compatible. For more information on system requirements, visit www.tandemdiabetes.com/updater.

## **Remote Software Updates for Insulin Pumps**

Tandem is the only company with a tool for providing remote software updates for its insulin pumps using a personal computer. The power of the t:slim X2 Pump's touchscreen allows for buttons to be moved and data like the interactive CGM screen to be added via software updates without getting a new device. With innovations in diabetes technology consistently moving faster than the typical insurance pump replacement cycle, remote software updates make it easier to make a purchasing decision today without worrying that the device will soon be outdated. Future Tandem products are being developed with software updates in mind, with the goal of delivering new technologies to both new and current customers at the same time.<sup>2</sup>

## The Benefits of Insulin Pump Therapy with CGM

Published studies have shown that insulin pump therapy, when paired with proper training and support, can result in better blood sugar control and lower total daily insulin use compared to multiple daily injections.<sup>6,7,8</sup> CGM has demonstrated improved blood sugar control, increased confidence related to the risk of low blood sugar, and decreased diabetes stress.<sup>9,10</sup> Combining insulin pump therapy and CGM has demonstrated the best overall glucose control compared to multiple daily injections or pump therapy alone, in addition to the quality of life improvements associated with each individual therapy.<sup>9</sup>

#### **Insulin Pump Use and Diabetes**

Diabetes is a chronic, life-threatening disease that affects more than 29 million people in the United States, or nearly 1 in 10 Americans. Tandem estimates that more than 3 million people in the United States require daily administration of insulin and are candidates for pump therapy. More than 425,000 Americans with type 1 diabetes use an insulin pump, or approximately 27% of the type 1 diabetes population. In addition, approximately 125,000 Americans with type 2 diabetes use an insulin pump, a small fraction of the type 2 diabetes population.

The t:slim X2 Pump with Dexcom G5 Mobile CGM integration will replace the Company's previous-generation t:slim G4<sup>™</sup> Pump. The Company will continue to service all current t:slim G4 Pumps for the duration of their warranty. An upgrade program is available through September 30, 2017, for t:slim and t:slim G4 Pump users interested in accessing the t:slim X2 Pump. For more information, visit <u>www.tandemdiabetes.com/upgrade</u>.

#### About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (<u>www.tandemdiabetes.com</u>) 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<sup>™</sup> Insulin Pump, the only pump capable of remote feature updates using a personal computer, and the t:flex® Insulin Pump, the first pump designed for people with greater insulin requirements. Tandem is based in San Diego, California.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #tslimX2, #tslimG4, #tflex, #tconnect, and \$TNDM. Follow Tandem Diabetes Care on Facebook at <u>www.facebook.com/TandemDiabetes</u>. Follow Tandem Diabetes Care on LinkedIn at <u>https://www.linkedin.com/company/tandemdiabetes.</u>

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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 include statements regarding the Company's ability to develop software updates that add automated insulin delivery algorithms to the t:slim X2 and the potential for faster integration with Dexcom products in the future. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including the Company's ability to complete the development of automated insulin delivery algorithms for the t:slim X2, the Company's ability to successfully complete clinical trials for new products when anticipated (or at all), the potential that the results of any such clinical trials may not be sufficient to support regulatory approvals for new products as anticipated and the Company's ability to obtain regulatory approvals for future

products and product features generally. 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 CGM-based treatment requires fingersticks for calibration; may result in hypoglycemia if calibration not performed, when taking acetaminophen, or if symptoms/expectations do not match CGM readings.
- <sup>2</sup> Additional feature updates are not currently available for the t:slim X2 Pump with Dexcom G5 Mobile CGM integration and are subject to future FDA approvals. Charges may apply.
- 3 38% smaller than MiniMed 630G and 670G and at least 28% smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.
- 4 Tested to 3 feet for 30 minutes (IPX7 rating).
- 5 dQ&A USA Diabetes Connections Surveys, 2009-2016.
- 6 Reznik Y, Cohen O, Aronson R, et al. Lancet. 2014;384(9950):1265-1272.
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- 10 Polonsky B, Hessler D, Ruedy K, Beck R. & DIAMOND Study Group. Diabetes Care. 2017. doi:10.2337/dc17-0133. [Epub ahead of print]

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