

# Tandem Diabetes Care Announces FDA Clearance of the t:flex<sup>™</sup> Insulin Pump

## Largest-capacity Insulin Pump Cleared for People with Greater Insulin Needs

SAN DIEGO, Jan. 12, 2015 /PRNewswire/ -- Tandem Diabetes Care<sup>®</sup>, Inc. (NASDAQ: TNDM), a medical device company and manufacturer of the t:slim<sup>®</sup> Insulin Pump, today announced that the U.S. Food and Drug Administration (FDA) has granted the Company clearance to market the t:flex<sup>™</sup> Insulin Pump. At 480 units, the insulin reservoir of the t:flex Pump has the largest capacity currently available in the United States.

"In recognizing that one size does not fit all, the t:flex Pump was developed using Tandem's proprietary technology platform to bring t:slim's benefits to people with greater insulin needs," said Kim Blickenstaff, President and Chief Executive Officer of Tandem Diabetes Care. "This first expansion of our product portfolio reflects our ongoing commitment to deliver user-friendly products that address unmet needs in the diabetes community."

People with diabetes require different amounts of insulin based on their level of insulin sensitivity, which can vary significantly from person to person. The t:flex Pump is designed for people who require more than 100 units of U-100 insulin per day, such as teenagers with type 1 diabetes and many people with type 2 diabetes. The pump offers people with greater insulin needs the benefits of pump therapy without the frequent reservoir changes required by 200- and 300-unit capacity pumps. It incorporates the same slim design, advanced Micro-Delivery<sup>™</sup> technology, and simplæ-use, touch-screen interface as the t:slim Insulin Pump, which is rated #1 by pump users.[1]

The t:flex Pump is expected to launch in the United States in the second quarter of 2015. People interested in more information about the t:flex Pump can visit the Company website at <u>www.tandemdiabetes.com/tflex</u>. The Company will report its fourth quarter and year-end 2014 financial results later in the first quarter, and anticipates providing guidance for 2015, including initial commercialization objectives for the t:flex Pump, at that time.

### 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 3 million people in the United States require daily administration of insulin and are candidates for pump therapy. More than 400,000 Americans with type 1 diabetes use an insulin pump, or approximately 27% of the type 1 diabetes population. In addition, approximately 75,000 Americans with type 2 diabetes use an insulin pump, a small fraction of the type 2 diabetes population.

Recent studies suggest that insulin pump therapy reduces average blood glucose levels and overall insulin needs in people with type 2 diabetes compared with standard therapy using multiple daily injections.[2] In Tandem's market research, two-thirds of endocrinologists cited limited capacity as the number one barrier to insulin pump adoption for people with type 2 diabetes who are insulin dependent.

### About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (<u>www.tandemdiabetes.com</u>) 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® Insulin Pump, the slimmest and smallest durable insulin pump currently on the market, and the t:flex<sup>™</sup> Insulin Pump, the first pump designed for people with greater insulin requirements. Tandem is based i San Diego, California.

### **Forward Looking Statement**

This press release includes forward-looking statements relating to the anticipated timing of the commercial launch of the t:flex Pump and the potential advantages of the t:flex Pump over existing insulin pumps. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including: Tandem's ability to begin commercial scale manufacturing of the t:flex Pump and associated cartridges; the potential that newer products that compete with the t:flex Pump, or other technological breakthroughs for the monitoring, treatment or prevention of diabetes, may render the t:flex Pump obsolete or less desirable; and other risks identified in Tandem's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. 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 any forward-looking statement in this press release.

The t:flex Insulin Pump is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of

diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes, use #tslim, #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>

t:slim, and Tandem Diabetes Care are registered trademarks, and t:flex is a trademark of Tandem Diabetes Care, Inc.

#### [1] dQ&A Patient Panel, Q2 2014

[2] Aronson Ronnie, Cohen Ohad, Conget Ignacio, Runzis Sarah, Castaneda Javier, de Portu Simona, Lee Scott, Reznik Yves, and for the OpT2mise Study Group. Diabetes Technology & Therapeutics. July 2014, 16(7): 414-420. doi:10.1089/dia.2013.0363.



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