

## **Tandem Diabetes Care Announces Health Canada Approval of t:slim X2 Insulin Pump with Basal-IQ Predictive Low-Glucose Suspend Technology**

November 20, 2019

SAN DIEGO--(BUSINESS WIRE)--Nov. 20, 2019-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced Health Canada approval of the t:slim X2™ insulin pump with Basal-IQ™ technology. Basal-IQ technology, a predictive low-glucose suspend (PLGS) algorithm, utilizes sensor values from an integrated Dexcom G6 continuous glucose monitor (CGM) to help reduce the frequency and duration of low-glucose events (hypoglycemia). All in-warranty t:slim X2 pump users in Canada will have the option to add Basal-IQ technology to their existing pump free of charge via remote software update in February 2020.<sup>1</sup> Tandem expects to begin shipping t:slim X2 pumps with Basal-IQ technology to new customers in the first quarter of 2020.

"The t:slim X2 insulin pump with Basal-IQ technology has received overwhelmingly positive feedback from current users and we are thrilled to bring its benefits to our customers in Canada," said John Sheridan, president and CEO of Tandem Diabetes Care. "Our ability to provide in-warranty t:slim X2 pump users a software update to add Basal-IQ technology to their current pumps using a personal computer is unparalleled in the industry and further differentiates the t:slim X2 insulin pump from other devices on the market."

### **Benefits of Basal-IQ Technology:**

**Predicts and helps prevent lows** – Using Dexcom G6 CGM values, the Basal-IQ feature looks ahead 30 minutes and suspends insulin when glucose is predicted to drop below 4.4 mmol/L (80 mg/dL) or if glucose is currently below 3.9 mmol/L (70 mg/dL). The system resumes insulin once sensor glucose values start to rise.

**No fingersticks\*** – With Dexcom G6 CGM integration, the Basal-IQ feature works with no fingersticks required for mealtime dosing or calibration. Other benefits of the Dexcom G6 CGM include an extended 10-day wear, acetaminophen blocking<sup>2</sup>, and the ability to share real-time CGM data with up to 10 followers.<sup>3</sup>

**Works silently in the background** – No additional alerts or alarms are required to use Basal-IQ technology compared to standard CGM-enabled pumps. Users can choose whether or not to receive alerts when insulin is suspended and resumed based on their personal preference.

**No complicated modes to manage** – The Basal-IQ feature has no complicated settings to manage and operates without constant input or interaction. The user only has to decide whether they want the feature on or off.

### **Standard Features of the t:slim X2 Insulin Pump:**

**Small and discreet** – The t:slim X2 pump is up to 38 percent smaller than other pumps<sup>4</sup>, yet can hold up to 300-units of insulin.

**Can be used with or without the Basal-IQ feature or CGM** – When advanced features are turned off, the t:slim X2 pump removes the CGM chart from the screen and puts the Bolus and Option buttons front and center for easy access.

**For additional product availability and safety information in Canada,  
visit [www.tandemdiabetes.ca](http://www.tandemdiabetes.ca).**

### **Free Demo App – Basal-IQ Technology Coming Soon**

Using the free t:simulator™ app, people will soon be able to experience the touchscreen interface of the t:slim X2 pump with Basal-IQ technology directly on their mobile device. For more information and to download the app, visit <http://www.tandemdiabetes.com/tsimulator>.

### **Free Software Update for Current t:slim X2 Pump Users**

All in-warranty t:slim X2 pump users in Canada will have the option to add the Basal-IQ feature free of charge via a software update using a personal computer. Current in-warranty t:slim X2 pump users in Canada will receive emails in the next few weeks with more information about the process, including a link to a 30 to 45-minute online training module which must be completed prior to updating their pump. Internet and computer access are required for pump updates. Tandem expects the Basal-IQ software update to be available for current t:slim X2 pump users in February 2020. Information about the requirements and update process is available at [www.tandemdiabetes.com/update](http://www.tandemdiabetes.com/update).

### **Basal-IQ Technology – Clinical Outcomes**

In a six-week pivotal trial (n=103), a randomized crossover study comparing two three-week periods of at-home insulin pump use, one period using the t:slim X2 pump with Basal-IQ technology, and another period using a CGM-integrated t:slim X2 pump without automated insulin suspension, use of Basal-IQ technology reduced the number of sensor glucose readings below 3.9 mmol/L (70 mg/dL) by 31 percent compared to the control period using a standard CGM-integrated t:slim X2 pump without automated insulin suspension. Importantly, this marked reduction of sensor time below 3.9 mmol/L (70 mg/dL) was accomplished without any increase in the rate of hyperglycemia and participants overwhelmingly described the system as simple to learn and use.<sup>5</sup> Data published on real-world use of Basal-IQ technology has demonstrated even greater reductions in time spent below 3.9 mmol/L (70 mg/dL) than seen in the pivotal trial.<sup>6</sup>

### **Diabetes in Canada**

According to Diabetes Canada ([www.diabetes.ca](http://www.diabetes.ca)), there are more than 3.4 million Canadians living with diabetes, of which approximately 10 percent have type 1 diabetes.<sup>7</sup> Insulin pumps and diabetes supplies are a covered benefit for qualifying recipients of disability tax credit, assistive devices

programs, and qualifying expenses for registered disability savings plans offered in various forms across Canadian provinces.<sup>8</sup>

### **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 with Basal-IQ™ technology. The t:slim X2 pump is capable of remote feature updates using a personal computer and is the only automated insulin delivery device approved for children as young as 6 years old. Tandem is based in San Diego, California.

Tandem Diabetes Care and Basal-IQ are trademarks of Tandem Diabetes Care, Inc., registered in the United States and other countries. t:slim X2 and t:simulator are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are trademarks of Dexcom, Inc., registered in the United States and other countries. All other third-party marks are the property of their respective owners.

### **Important Safety Information for the t:slim X2 Insulin Pump with Basal-IQ Technology**

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. The t:slim X2 insulin pump with Basal-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Basal-IQ technology, and a compatible CGM. CGM sold separately. The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When the System is used with a compatible iCGM, Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. The System is indicated for use in individuals 6 years of age and greater. The System is intended for single patient use. The System is indicated for use with NovoLog/NovoRapid or Humalog U-100 insulin. The System is not approved for use in pregnant women, persons on dialysis, or critically ill patients. The pump is not intended for anyone unable or unwilling to: use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; and see their healthcare provider regularly. The user must also have adequate vision and/or hearing to recognize all functions of the pump, including alerts. For detailed indications for use and safety information, visit [tandemdiabetes.com/safetyinfo](http://tandemdiabetes.com/safetyinfo).

### **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 timing for the commercial launch of the t:slim X2 pump with Basal-IQ technology in Canada and our ability to offer the Basal-IQ software update for current t:slim X2 pump users in Canada. These statements are subject to numerous risks and uncertainties, including our ability to obtain and retain registration as an approved vendor for provincial device reimbursement programs, our ability to fulfill commercial demand for the t:slim X2 with Basal-IQ technology, our ability to facilitate online training for existing t:slim X2 customers upgrading their devices, and the risk that we may encounter other challenges that may delay the commercial launch of the t:slim X2 pump with Basal-IQ technology in Canada, 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.

\* If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. Dexcom G6 CGM sold separately.

<sup>1</sup> Additional training is required for this software update.

<sup>2</sup> Dexcom G6 CGM readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000mg every 6 hours. Taking a higher dose may affect the G6 readings.

<sup>3</sup> Separate Follow App required.

<sup>4</sup> 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.

<sup>5</sup> Forlenza GP, Li Z, Buckingham BA, Pinsker JE, et al. Predictive low glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial. *Diabetes Care*. 2018;41(10): 2155-2161. DOI:10.2337/dc18-0771.

<sup>6</sup> Muller L, Habif S, Leas S, Aronoff-Spencer E. Reducing Hypoglycemia in the Real World: A Retrospective Analysis of Predictive Low-Glucose Suspend Technology in an Ambulatory Insulin-Dependent Cohort. *Diab Technol Ther*. 2019;21(9):474-484. DOI: 10.1089/dia.2019.0190

<sup>7</sup> Estimated diabetes statistics in Canada are generated by the Canadian Diabetes Cost Model; 2015.

<sup>8</sup> <http://www.diabetes.ca/about-cda/public-policy-position-statements/access-to-diabetes-medication-supplies-medical-devices>.

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Source: Tandem Diabetes Care, Inc.

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