Abbott And Tandem Diabetes Care Advance Development Of Integrated Technologies For Future Automated Insulin Delivery Systems

- Companies partner to integrate Abbott's FreeStyle Libre continuous glucose monitoring technology with Tandem's insulin delivery products to provide options to simplify and tailor diabetes management

ABBOTT PARK, Ill. and SAN DIEGO, June 29, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) and Tandem Diabetes Care (NASDAQ: TNDM) announced today that they have finalized an agreement to develop and commercialize integrated diabetes solutions that combine Abbott's world-leading[1] continuous glucose monitoring (CGM) technology with Tandem's innovative insulin delivery systems to provide more options for people to manage their diabetes. The companies first announced their intention to work together in October 2019, and this resulting agreement covers the technical development of device integration and associated commercial support activities.

"We're excited to integrate our insulin delivery systems with Abbott's glucose-sensing technology, and we look forward to expanding options for our customers so that they can combine devices that best suit their personal needs," said John Sheridan, president and CEO of Tandem Diabetes Care. "We are proud to have an insulin pump capable of remote software updates that can make access to future integrations possible for in-warranty t:slim X2 users at the time of release without requiring a new pump."

The need for interoperability between diabetes devices is widely recognized. Tandem's t:slim X2™ insulin pump was the first to receive U.S. Food and Drug Administration (FDA) clearance in a new device category called alternate controller enabled (ACE) infusion pumps in 2019. The special controls for ACE pumps allow for reliable and secure communication with compatible external devices. Abbott's FreeStyle Libre 2 integrated continuous glucose monitoring (iCGM) system was recently cleared by the FDA for adults and children (4 years and older). Through this collaboration, Abbott and Tandem will work to digitally connect their technologies for future automated insulin delivery systems, which will provide people with options to tailor and simplify how they manage their diabetes.[2]

"Abbott is working with our partners to bring integrated technologies at an affordable price for people with diabetes who rely on using insulin pumps," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "By combining our glucose sensing technology with Tandem's proven insulin delivery systems, we will be able to create a cohesive ecosystem for people with diabetes that can fit easily into their daily lives."

The companies will focus initial commercial activities in the U.S. and Canada with additional geographies considered in the future.

About the FreeStyle Libre 2 System
Abbott's FreeStyle Libre 2 system was recently cleared by the U.S. Food and Drug Administration (FDA) as an integrated continuous glucose monitoring (iCGM) system for adults and children ages 4 and older with diabetes. It is the only iCGM system with optional real-time alarms[3] that measures glucose levels every minute, meeting the highest level of accuracy standards.[4] The FreeStyle Libre 2 next-generation sensor is worn on the back of the upper arm for up to 14 days and with a one-second scan using a handheld reader, users can see their glucose reading, trend arrow and eight-hour history.

As the #1 sensor-based glucose monitoring system used in the U.S. and worldwide,[5] Abbott's FreeStyle Libre portfolio has changed the lives of more than 2 million people across 50 countries by providing breakthrough technology that is accessible and affordable.[6] Abbott has secured partial or full reimbursement for the FreeStyle Libre system in 36 countries, including Canada, France, Germany, Japan, the United Kingdom and the U.S.

Indications and Important Safety Information – FreeStyle Libre 2 System
The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real-time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

WARNINGS/LIMITATIONS*:

The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems. Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment. Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings. Failure to use the System according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value to make diabetes treatment decisions. Seek medical attention when appropriate and contact Abbott Toll Free (855-632-8658) or visit* www.freestylelibre.us for detailed indications for use and safety information.

*Please refer to www.freestylelibre.us for the indications and important safety information.

About the t:slim X2 Insulin Pump
The t:slim X2 pump was the first insulin pump classified by the FDA in a new device category called alternate controller enabled (ACE) infusion pumps[7] and the first system approved as compatible with interoperable continuous glucose monitoring (iCGM) devices. The system includes advanced features like a large color touchscreen, rechargeable battery, *Bluetooth®* wireless technology, USB connectivity and watertight construction (IPX7).[8] It is capable of remote software updates using a personal computer, offering the potential for in-warranty users to access new features as they become available.[9]

Indications and Important Safety Information – t:slim X2 Insulin Pump
RX ONLY. The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. 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. The pump is indicated for use in individuals six years of age and greater. The pump is intended for single patient, home use and requires a prescription. The pump is indicated for use with NovoLog or Humalog U-100 insulin. The t:slim X2 pump must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com, on LinkedIn at www.linkedin.com/company/abbott-/, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

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, Calif.

Connect with Tandem Diabetes Care at www.tandemdiabetes.com, on Twitter @tandemdiabetes, on Facebook at www.facebook.com/TandemDiabetes, and on LinkedIn at www.linkedin.com/company/TandemDiabetes.

Tandem Diabetes Care is a registered trademark and t:slim X2 is a trademark of Tandem Diabetes Care, Inc. The Bluetooth word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Tandem Diabetes Care, Inc. is under license.

Forward Looking Statement – Tandem Diabetes Care
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 development plans to integrate Tandem insulin delivery systems with Abbott glucose-sensing technology, create cohesive ecosystems and commercialize the products for use in automated insulin delivery systems, as well as Tandem's ability to offer remote software updates. These statements are subject to numerous risks and uncertainties, including the risks that technical challenges, clinical or regulatory hurdles or other factors may prevent or delay integration/interoperability and that the agreement between the companies could be terminated. These and other risks and uncertainties are identified in Tandem's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively, and other documents filed by Tandem 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] Data on file, Abbott Diabetes Care. Data based on the number of users worldwide for the FreeStyle Libre system compared to the number of users for other leading personal use, sensor-based glucose monitoring systems.

[2] The FreeStyle Libre 2 system is currently not indicated for use with automatic insulin delivery systems. Future uses for the FreeStyle Libre 2 System are under development and are subject to FDA clearance.

[3] Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

[4] Based on FDA iCGM special controls.

[5] Data on file, Abbott Diabetes Care. Data based on the number of users worldwide for the FreeStyle Libre system compared to the number of users for other leading personal-use, sensor-based glucose monitoring systems.

[6] Based on a comparison of list prices of the FreeStyle Libre 14 day system versus competitors' CGM systems. FreeStyle Libre 2 system will be list priced the same rate as FreeStyle Libre 14 day system. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any.

[7] U.S. Food and Drug Administration. *FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices*; 2019. Available at https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through. Accessed October 14, 2019.

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

[9] Additional feature updates are subject to future FDA approvals. A prescription and additional training may be required to access certain future software updates.

SOURCE Abbott

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