Abbott's FreeStyle® Libre 2 ICGM Cleared In U.S. For Adults And Children With Diabetes, Achieving Highest Level Of Accuracy And Performance Standards

- FreeStyle Libre 2 is the only integrated continuous glucose monitoring (iCGM) system available that continuously transmits glucose data every minute with customizable, optional real-time alarms to alert users when their glucose is high or low without scanning

- Now for children (ages 4 and older) and adults with diabetes, this latest technology is the first and only iCGM that sustains performance for up to 14 days, providing trends, insights and actionable data

- FreeStyle Libre 2 system includes a self-applied sensor (the size of two-stacked quarters) that is easiest glucose sensor to apply[1] and worn on the back of the upper arm, eliminating the need for painful fingersticks to test glucose levels[2]

- FreeStyle Libre portfolio has been extensively studied with the most real-world users, delivering proven health outcomes[3]

- FreeStyle Libre 2 system offers enhanced features at the same affordable price as FreeStyle Libre 14 day system, which is a third of the cost of other CGMs[4]

ABBOTT PARK, Ill., June 15, 2020 /PRNewswire/ -- Abbott (NYSE: ABT), the worldwide leader in continuous glucose monitoring (CGM), announced today the U.S. Food and Drug Administration (FDA) cleared its next-generation FreeStyle® Libre 2 integrated continuous glucose monitoring (iCGM) system for adults and children ages 4 and older with diabetes. This is the only iCGM system with optional real-time alarms that measures glucose levels every minute, meeting the highest level of accuracy standards[5] over 14 days, including superior day one[1] accuracy compared to the other iCGM and excellent accuracy and alarm performance at low end glucose levels.[6] With a 14-day wear time, the FreeStyle Libre 2 system is the longest-lasting, self-applied iCGM sensor currently available, eliminating the need for fingersticks[2]– and priced at a third of the cost of other CGM systems.[4]

"We're thrilled to bring our next generation technology on our world-leading sensing platform to both children and adults with diabetes in the U.S.," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "With unsurpassed 14-day accuracy and enhanced features including optional alarms at a fraction of the cost of other CGMs, Abbott's FreeStyle Libre 2 system will change the future of diabetes care in the U.S. the same way it has around the globe."

Using Bluetooth technology, the FreeStyle Libre 2 system automatically alerts users when their glucose is high or low without needing to scan the sensor. Users also have the option of turning off the customizable, real-time alarms.[7] The system has a combined mean absolute relative difference (MARD), a measurement of performance for CGMs, of 9.3% (9.2% for adults and 9.7% for pediatrics), making it the only iCGM sensor sustaining a high level of accuracy over 14 days.

"Innovations like FreeStyle Libre 2 will change the way people manage their diabetes, especially among children," said Larry Kurt Midyett, M.D., pediatric endocrinologist, Midwest Women's and Children's Specialty Group. "Using this technology can improve time in optimal glucose range and lower HbA1c because we can get a full picture of what a child's glucose levels are doing without having to disrupt their play or sleep with painful fingersticks. The alarms are a bonus because they provide parents a level of reassurance."

The FreeStyle Libre 2 system met or exceeded the FDA's rigorous iCGM special control standards. The system is designed to digitally connect and communicate with other devices. This can allow people to tailor and potentially simplify how they manage their diabetes.

The FreeStyle Libre 2 next-generation sensor, which is a third less bulky than other CGM sensors[1], is worn on the back of the upper arm for up to 14 days and measures glucose every minute to help users and their healthcare providers make informed treatment decisions. With a one-second scan using a handheld reader, users can see their glucose reading, trend arrow and eight-hour history. It is also designed for use with a mobile app, which Abbott is working to bring to the U.S. market.

The FreeStyle Libre 2 system will be available in the coming weeks at participating pharmacies and durable medical equipment suppliers (DMEs) across the U.S. Abbott will offer the new system at the same price as the currently available FreeStyle Libre 14 day system, which was approved by the FDA in July 2018.

"Managing diabetes is expensive, even for those with insurance coverage," said Watkin. "From the start, Abbott designed FreeStyle Libre technology with affordability in mind. We set a global price for our sensing technology that's closer to that of traditional blood glucose fingerstick systems, and significantly less than other CGMs, because we wanted to make sure our life-changing technology was accessible to as many people as possible."

As the #1 sensor-based glucose monitoring system used in the U.S. and worldwide[8], Abbott's FreeStyle Libre portfolio has changed the lives of more than 2 million people across 50 countries[5] by providing breakthrough technology that is accessible and affordable.[4] 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

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.*

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 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.

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[1] Data on file, Abbott Diabetes Care.

[2] Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.

[3] Eeg-Olofsson, Katarina et al. Real-world study of FreeStyle Libre system among adults with Type 1 and Type 2 diabetes within the Swedish National Diabetes Register. Poster presented at ATTD, February 2020.

[4] 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.

[5] Based on FDA iCGM special controls.

[6] FreeStyle Libre 2 User Manual. Based on low glucose alarms set at 70 mg/dl.

[7] Consult with healthcare professional before turning off alarms. When alarms are turned off, notification will not be received during low or high glucose.

[8] 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.

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