Abbott's FreeStyle® Libre 14 Day System Now Available In U.S. For Hospitalized Patients With Diabetes During COVID-19 Pandemic

-- More than 50% of people with diabetes who have been diagnosed with COVID-19 are hospitalized, according to a report from the Centers for Disease Control and Prevention (CDC)[1]

-- FreeStyle Libre 14 day system can be used by frontline healthcare workers in hospitals to remotely monitor patients with diabetes who can scan[2] to minimize exposure to COVID-19 and preserve use of personal protective equipment (PPE)

-- In partnership with the American Diabetes Association (ADA), Abbott will donate 25,000 FreeStyle Libre 14 day sensors to U.S. hospitals and medical centers in outbreak hotspots to help accelerate access to technology

ABBOTT PARK, Ill., April 8, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the FreeStyle Libre 14 day system, the world's leading[3] continuous glucose monitoring (CGM) technology, can now be used in the hospital setting[2] during the COVID-19 pandemic, according to the U.S. Food and Drug Administration (FDA). This will permit frontline healthcare workers to remotely monitor patients with diabetes receiving inpatient care by assessing real-time glucose levels[4] and glucose history. To help hospitals and medical centers in COVID-19 outbreak hotspots ramp up access to the technology, Abbott will donate 25,000 FreeStyle Libre 14 day sensors in partnership with the American Diabetes Association (ADA), Insulin for Life USA and Diabetes Disaster Response Coalition.

According to a recent report[1] by the Centers for Disease Control and Prevention (CDC), more than 50% of people with diabetes who have been diagnosed with COVID-19 are hospitalized.

"There's been a spike in demand for health technology as hospitals are looking for ways to minimize COVID-19 exposure, especially to high-risk patients such as people with chronic conditions like diabetes," said Eugene E. Wright, Jr., M.D., medical director for performance improvement, Charlotte Area Health Education Center in North Carolina. "Having access to technology like FreeStyle Libre 14 day system allows physicians to keep a close eye on hospitalized patients while minimizing transmission risks, PPE use and contact with hospital staff."

With a one-second scan using a reader or smartphone[5] over the FreeStyle Libre 14 day sensor worn on the back of the upper arm, users get real-time glucose readings every minute, historical trends and patterns, and arrows showing where glucose levels are going without having to fingerstick[6]. At the same time, physicians will receive real-time glucose data and actionable information to help make important treatment decisions through LibreView[7], a secure, cloud-based diabetes management system. Recent studies showed that users of the FreeStyle Libre 14 day system have improved glucose control[8], decreased time in hyperglycemia[9] and hypoglycemia[10] as well as reduced hospitalizations[11], and HbA1C[12] levels.

"We appreciate the FDA's quick action to make medical products available during this public health crisis," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "By working with our partners at the American Diabetes Association to arm frontline healthcare workers with FreeStyle Libre technology, Abbott will enable them to protect and monitor their patients with diabetes, limit COVID-19 exposure and also manage the influx of critical care needs."

For more information about using FreeStyle Libre 14 day system in the hospital, please contact 1-800-401-1183.

About FreeStyle Libre Portfolio

As the #1 sensor-based glucose monitoring system used worldwide[3], Abbott's FreeStyle Libre portfolio has changed the lives of more than 2 million people across 46 countries[13] by providing breakthrough technology that is accessible and affordable[14]. It is priced at one-third[14] of other continuous glucose monitoring systems available today. Abbott has also secured partial or full reimbursement for the FreeStyle Libre system in 36 countries, including Canada, Japan, the United Kingdom, and the U.S. For more information, please visit www.freestylelibre.us.

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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INDICATIONS AND IMPORTANT SAFETY INFORMATION

FreeStyle Libre and FreeStyle Libre 14 day Flash Glucose Monitoring systems are continuous glucose monitoring (CGM) devices indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The systems are intended for single patient use and require a prescription.

CONTRAINDICATIONS: Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. When using FreeStyle LibreLink app, access to a blood glucose monitoring system is required as the app does not provide one. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit www.freestylelibre.us for detailed indications for use and safety information.

[1] Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020. MMWR Morb Mortal Wkly Rep 2020;69:382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6913e2 external icon.

[2] Patients must be able to scan their FreeStyle Libre 14 day sensor by themselves.

[3] 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

[4] The user must be connected to data services for glucose data to automatically upload to LibreView.

[5] The FreeStyle LibreLink app is compatible with NFC-enabled smartphones running Android OS 5.0 or higher and iPhone 7 or later running iOS 11 or later. Use of the FreeStyle LibreLink app requires registration with LibreView, a service provided by Abbott and Newyu, Inc.

[6] Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.

[7] LibreView is developed, distributed, and supported by Newyu, Inc. The LibreView data management software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management. The LibreView software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

[8] Haak, Thomas, et al. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. Diabetes Therapy 8.1 (2017): 55-73r

[9] Acute diabetes complications defined by hypoglycemia, hypoglycemic coma, hyperglycemia, ketoacidosis, or hyperosmolarity ICD-10 codes as primary diagnosis for inpatient or as any position in the outpatient emergency claim; Matthew Kerr, Gregory Roberts, Diana Souto, Yelena Nabutovsky

[10] Bolinder, Jan, et al. Novel glucose-sensing technology and hypoglycemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. The Lancet 388.10057 (2016): 2254-2263.

[11] Fokkert M, van Dijk P,Edens M, et al. Improved wellbeing and decreased disease burden after 1-year use of flash glucose monitoring (FLARENL4). BMJ Open Diab Res Care 2019;7:e000809. doi:10.1136/bmjdrc-2019-000809.

[12] Improving HbA1c control in people with Type 1 or Type 2 diabetes using flash glucose monitoring: a retrospective observational analysis in two German centers; Gerhard Klausmann, Ludger Rose, Alexander Seibold

[13] Data on file, Abbott Diabetes Care

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

SOURCE Abbott

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