ABBOTT'S FREESTYLE® LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM NOW APPROVED IN U.S.

- ALLOWS USERS TO WEAR THE SENSOR FOR UP TO 14 DAYS WITH HIGH ACCURACY

- FREESTYLE LIBRE 14 DAY NOW THE LONGEST-LASTING SELF-APPLIED CONTINUOUS GLUCOSE SENSING TECHNOLOGY AVAILABLE

- FREESTYLE LIBRE SYSTEM NOW BEING USED BY MORE THAN 800,000 PEOPLE WITH DIABETES GLOBALLY AND IS THE WORLD'S #1 CGM SYSTEM[1]

ABBOTT PARK, Ill., July 27, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved the FreeStyle® Libre 14 day Flash Glucose Monitoring system, which allows people with diabetes to wear the sensor up to 14 days with high accuracy. This approval makes Abbott's revolutionary continuous glucose monitor (CGM) the longest lasting self-applied personal glucose sensor available on the market.

"At Abbott, we are continuously pushing for new innovations that minimize the daily burden of managing diabetes," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "With the new FreeStyle Libre 14 day system, people with diabetes will now have extended access to their glucose data with a high degree of accuracy, which will improve their experience and help empower them to better manage their condition."

HOW THE FREESTYLE LIBRE SYSTEMS WORK

The FreeStyle Libre system, which first launched in Europe in 2014, with a 14-day wear time, was the first to eliminate the need for fingersticks[10], and is designed to be an easier-to-use[2], streamlined[3] and more affordable system[4] compared with other available CGMs on the market. In the U.S., the FreeStyle Libre system (10 day) is approved for replacement[2] of blood glucose monitoring (BGM) for adults with diabetes. With just a quick, one-second scan, users can see real-time glucose readings, as well as identify glucose trends with a directional arrow and review eight hours of glucose history. The sensor is worn on the back of the upper arm and is the size of two stacked quarters.

The FreeStyle Libre system is supported by both clinical data[5,6] and real-world evidence[7] that show that people who scan more frequently spend less time in hypoglycemia (low-glucose levels) or hyperglycemia (high-glucose levels) while having improved average glucose levels, demonstrating improved glucose control overall.

The FreeStyle Libre 14 day system has a 1-hour warmup and greater accuracy compared to the FreeStyle Libre system (10 day) with a mean absolute relative difference (MARD) of 9.4 compared to 9.7, respectively. The FreeStyle Libre system (10 day) was approved by the FDA in September 2017.

The FreeStyle Libre 14 day system will be available via prescription in the coming months at participating pharmacies and durable medical equipment suppliers (DMEs) in the U.S.

FreeStyle Libre system is now being used by more than 800,000 people across more than 43 countries[8] and is the #1 CGM worldwide[9]. Additionally, Abbott has secured partial or full reimbursement for the FreeStyle Libre system in 30 countries, including France, Japan, the United Kingdom and the U.S.

For more information, please visit: www.freestylelibre.us.

About Abbott
At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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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 systems do not have alarms unless the sensor is scanned, and the systems contain small parts that may be dangerous if swallowed. The systems are 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.

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. For full indications for use and safety information, see more here.

[1] Data based on the number of users worldwide for FreeStyle Libre personal CGM compared to the number of users of other leading personal CGM brands.

[2] Data on file. Abbott Diabetes Care.

[3] Data on file. Abbott Diabetes Care.

[4] Data on file. Abbott Diabetes Care.

[5] 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): 55-73

[6] 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

[7] Pryor, Heather et al. Real-world Patterns of Daytime and Nocturnal Hypoglycemia during Flash Continuous Glucose Monitoring. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a7d4359

[8] Data on file. Abbott Diabetes Care

[9] Data based on the number of users worldwide for FreeStyle Libre personal CGM compared to the number of users for other leading personal CGM brands

[10] A finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or if hypoglycaemia or impending hypoglycaemia is reported by the system or when symptoms do not match the system readings.

SOURCE Abbott

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