

## New Real-World Evidence Analysis Of Nearly Half A Million FreeStyle® Libre System Users Shows Higher Rates Of Scanning Improves Glucose Control

- Data presented at ATTD confirms previous analyses that higher rates of scanning with the FreeStyle Libre system are strongly associated with improved glucose control
- Prolonged hypoglycemia reduced by up to 56 percent if users scan a second time within an hour of low glucose readings
- Trend arrow readings before meals can help identify glucose levels that can potentially be used to adjust treatment and address after meal hyperglycemia

BERLIN, Feb. 21, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced data from three real-world evidence studies that provide a comprehensive look at the global use of the FreeStyle Libre flash glucose monitoring system and its impact on health outcomes for people living with diabetes. The new real-world evidence analyses, which for the first time included data from the United States, highlighted key user benefits, including reduction in prolonged hypoglycemia and better glucose control when using both the glucose level and trend arrow during meal times. The data was presented today at the 12th Advanced Technologies & Treatments for Diabetes (ATTD) meeting in Berlin.

The expanded real-world evidence data set, which included nearly 500,000 of the more than 1.3 million FreeStyle Libre system users globally, also confirmed ongoing clinical benefits, including decreased time in hyperglycemia (high glucose levels) and hypoglycemia (low glucose levels), as well as increased time in optimal glucose range with frequent scanning. The FreeStyle Libre system reads glucose levels through a sensor that can be worn on the back of the upper arm, eliminating the need for fingersticks<sup>i</sup>.

"There is no better testament to the efficacy of the FreeStyle Libre system than seeing data that shows how people are using it in their day-to-day lives," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "Real-world evidence combined with data from clinical trials provide important perspectives on a product's value and best uses. Abbott has presented real-world data on hundreds of thousands of FreeStyle Libre users over the last several years, giving us deeper insights into how people are engaging with our technology and how that behavior is driving better health outcomes."

### Real-World Evidence Continues to Show Improved Glucose Control with Frequent Use of FreeStyle Libre System

The analysis of real-world use data of FreeStyle Libre system confirmed prior data findings that higher rates of scanning to self-monitor glucose strongly associate with improved glucose levels. With nearly 500,000 individuals using the device across 26 countries, findings include:

- Users performed an average of 12 scans per day to check their glucose level
- Estimated HbA1c (average glucose levels for 90 days) decreased from 8.2 percent to 6.7 percent as scan rate increased
- People who scanned frequently decreased time in hypoglycemia by 31 percent compared to people who did not scan frequently
- People who scanned frequently spent significantly less time in hyperglycemia during the day compared to lower frequency scanners

### Scanning a Second Time within One Hour Resulted in Decreased Time in Prolonged Hypoglycemia

A separate study identified that people who scanned a second time within 60 minutes of a low glucose event (below 70 mg/dl) with the FreeStyle Libre system reduced the likelihood of prolonged hypoglycemia by more than half (56 percent)<sup>iii</sup>. The analysis also found that waiting longer to complete the second scan increased the rate of prolonged hypoglycemia, which could increase risk of immediate, serious health complications from low glucose.

### Trend Arrow Readings Before Meals Can Help Identify Glucose Levels that Can be Used to Adjust Treatment and Address After Meal Hyperglycemia

A third analysis presented at ATTD found that it is important to pay attention not only to the glucose reading provided by the FreeStyle Libre system, but also to the trend arrows that tell users if their glucose levels are increasing, decreasing or staying steady<sup>iv</sup>. The study, which assessed nearly 15,000 users, found meaningful differences in hyperglycemia post-meal associated with different glucose levels and trend arrows at meals. The data confirms clinical guidance to proactively adjust therapy and other interventions such as diet and exercise based on FreeStyle Libre's trend arrows to prevent hyperglycemia and hypoglycemia<sup>v</sup>.

"The FreeStyle Libre system is fundamentally changing the way people manage their diabetes. Whether it is prompting people to make proactive adjustments based on trend arrows or keeping a careful eye on their low glucose levels, the results of these studies show that people become more engaged with their health with the right information," said Mahmood Kazemi, M.D., divisional vice president, Global Medical and Scientific Affairs, Diabetes Care, Abbott.

Abbott's FreeStyle Libre system is now being used by more than 1.3 million people living with diabetes across 46 countries. Abbott has secured partial or full reimbursement for the FreeStyle Libre system in 33 countries, including France, Ireland, Japan, the United Kingdom, and the U.S. For more information, please visit [www.freestylelibre.us](http://www.freestylelibre.us).

For the U.S. version of FreeStyle Libre system, the Indications and Important Safety Information is below.

### INDICATIONS AND IMPORTANT SAFETY INFORMATION

The FreeStyle Libre Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device 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 system is intended for single patient use and requires 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 FreeStyle Libre system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The FreeStyle Libre 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. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit [www.freestylelibre.us](http://www.freestylelibre.us) for detailed indications for use and safety information.

### About Abbott

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<sup>i</sup> 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.

<sup>ii</sup> Lang, SR Jangam et al, Expanded Real-world Use Confirms Strong Association between Frequency of Flash Glucose Monitoring and Glucose Control. Presented at the 12th Advanced Technologies & Treatments for Diabetes (ATTD) in Berlin, Germany. <https://cmoffice.kenes.com/cmsearchableprogrammeV15/conferencemanager/programme/personid/anonymous/attd19/normal/b833d15f547f3cf698a5e922754684fa334885ed#!abstractdetails/0000258110>

<sup>iii</sup> Danne, Thomas et al. Real-world reduction of prolonged hypoglycemia with flash glucose monitoring: the importance of scanning again within the next hour. Presented at the 12th Advanced Technologies & Treatments for Diabetes (ATTD) in Berlin, Germany. <https://cmoffice.kenes.com/cmsearchableprogrammeV15/conferencemanager/programme/personid/anonymous/attd19/normal/b833d15f547f3cf698a5e922754684fa334885ed#!abstractdetails/0000225240>

<sup>iv</sup> Jangam, Sujit R. et al. Pre-prandial glycaemic level and trend associations with post-prandial hyperglycaemia: A worldwide observational analysis. Presented at the 12th Advanced Technologies & Treatments for Diabetes (ATTD) in Berlin, Germany. <https://cmoffice.kenes.com/cmsearchableprogrammeV15/conferencemanager/programme/personid/anonymous/attd19/normal/b833d15f547f3cf698a5e922754684fa334885ed#!abstractdetails/0000258070>

<sup>v</sup> Kudva, Yogish C et al. Approach to Using Trend Arrows in the FreeStyle Libre Flash Glucose Monitoring Systems in Adults. Journal of the Endocrine Society, Volume 2, Issue 12, December 2018, Pages 1320–1337, <https://doi.org/10.1210/je.2018-00294>

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