New Data Show Use Of Abbott's FreeStyle® Libre System Significantly Reduces HbA1c Levels In People Living With Type 2 Diabetes

- Presented as a late-breaker at the American Diabetes Association (ADA) 79th Scientific Sessions, new real-world data demonstrate that monitoring glucose with FreeStyle Libre System has a positive impact among adults with Type 2 Diabetes who use multiple injections of insulin daily

- Findings represent the first ever evaluation of real-world evidence specifically from the subset of people with Type 2 diabetes using Abbott's FreeStyle Libre system

- Data underscore how actionable insights from the FreeStyle Libre system could help the more than 425 million people with diabetes[1] globally make better decisions to improve diabetes management

SAN FRANCISCO, June 8, 2019 /PRNewswire/ -- Today Abbott (NYSE: ABT) announced new data showing use of its FreeStyle Libre system, the company's revolutionary continuous glucose monitoring (CGM) technology, significantly reduced hemoglobin A1c (HbA1c) levels for people living with Type 2 diabetes on intensive insulin therapy.[2] The results were analyzed from retrospective, real-world data in three countries across Europe and presented as a late-breaker (Abstract 99-LB) at the American Diabetes Association (ADA) 79th Scientific Sessions in San Francisco.

The goal of the combined analysis of three individual studies was to determine the impact of using the FreeStyle Libre system on glycemic control in people on intensive insulin therapy living with Type 2 diabetes, the most common form of diabetes where the body is unable to make enough insulin to keep blood glucose levels normal. Researchers evaluated de-identified records of 363 individuals across France, Germany and Austria, assessing their HbA1c levels over three to six months in people averaging about 63 years in age who use insulin multiple times a day for an average of more than eight years.

The results – which represent the first time researchers evaluated real-world data specifically from people with Type 2 diabetes who use the FreeStyle Libre system[3] – showed lower HbA1c levels with the use of Abbott's technology after at least three months of use. The nearly 1% drop (-0.9% or -9.7 mmol/mol) in HbA1c represents a significant reduction of glucose levels toward the ADA's recommended A1c goal of 7% for adults with diabetes (not including women who are pregnant).[4]

Other notable findings showed:

- Average HbA1c was 8.9% (73.3 mmol/mol) prior to FreeStyle Libre system use and 8.0% (63.6 mmol/mol) following use of the technology.
- There were no differences detected based on age group, gender, body mass index or duration of insulin use, indicating the findings apply to the broad population of people with Type 2 diabetes and not just a particular subset.

"These real-world findings highlight how Abbott's FreeStyle Libre system can fundamentally change how people manage their diabetes, especially for people living with Type 2 diabetes," said Helene Hanaire, M.D., University Hospital Center of Toulouse in Toulouse, France, and one of the lead authors of the study. "By using the real-time results, trends and patterns from the technology right at their fingertips, people with diabetes are becoming more actively engaged in making better decisions to control their glucose levels and improve their own health."

Real-World Data and Clinical Research Emphasize the Role of the FreeStyle Libre System in Potentially Changing the Standard of Care

Hemoglobin A1c levels, which reflect a person's average blood sugar over a period of three months, serve as the gold standard to indicate a person's risk for developing long-term complications from diabetes. For people managing diabetes, the goal of reaching normal A1c levels is one of the critical success measurements because it is correlated with long-term health outcomes. This real-world data, coupled with a recently published independent randomized controlled trial study in *Diabetes Care*, further confirms that the use of FreeStyle Libre system significantly reduces HbA1c levels and improves glucose control in people with Type 2 diabetes.[5]

Additionally, growing evidence shows access to time in range (TIR) and reports like the Ambulatory Glucose Profile (AGP), which gives a more simplified and clear overview of glucose levels and patterns over time, can be valuable tools to improve glycemic control and enhance the standard of care in addition to HbA1c to better manage diabetes.

"Doctors tell us that FreeStyle Libre is changing the course of care for people with diabetes, and the combination of these real-world data and clinical research is further proof that our technology delivers significant reductions in HbA1c in people with Type 2 diabetes," said Mahmood Kazemi, M.D., divisional vice president, global medical and scientific affairs, Diabetes Care, Abbott. "This adds to growing evidence from more than half a million users in real-world settings showing time after time, use of FreeStyle Libre is associated with improved glucose control and better health outcomes. With more than 425 million people living with diabetes around the world, there's an immense opportunity for Abbott's technology to change more lives and the future of those with diabetes."

Abbott's FreeStyle Libre system is now being used by more than 1.5 million people living with diabetes across 46 countries.[6] 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. FreeStyle Libre 14 day system is also offered for Medicare patients in the U.S. based on

eligibility.[7] For more information, please visit 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 14 day 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 14 day 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 14 day 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 for detailed indications for use and safety information.

About Abbott
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[1] International Diabetes Federation. About Diabetes. https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html. Accessed May 2019.

[2] Kröger, J., Fasching, P, Hanaire, H, Meta-Analysis of Three, Real-World, Chart Review Studies to Determine the Effectiveness of FreeStyle Libre Flash Glucose Monitoring System on HbA1c in Adults with Type 2 Diabetes. Presented at the American Diabetes Association (ADA) 79th Scientific Sessions in San Francisco, California, USA.

[3] Compared to anonymized data evaluating records from both Type 1 and Type 2 patients.

[4] American Diabetes Association. A1C and eAG. http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/a1c/. Last accessed May 2019.

[5] Yaron, M. et al. Effect of Flash Glucose Monitoring Technology on Glycemic Control and Treatment Satisfaction in Patients with Type 2 Diabetes. *Diabetes Care.* Published online April 29, 2019.

[6] Data on file. Abbott Diabetes Care.

[7] For Medicare patients, please visit the Medicare Guide for more information. Patients must meet Medicare eligibility coverage criteria.

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