New Late-Breaking Data Show Use Of Abbott's FreeStyle® Libre System Significantly Reduces HbA1C Levels In People With Type 2 Diabetes Using Insulin Or Not

- Real-world data(1) presented at the American Diabetes Association 80th Scientific Sessions suggest people with type 2 diabetes can achieve similar outcomes to adding insulin therapy for both long-acting insulin or non-insulin users

- A separate late-breaking trial(2) demonstrates FreeStyle Libre portfolio use is associated with significant reductions of acute diabetes events and hospitalizations for a similar population

ABBOTT PARK, Ill., June 13, 2020 /PRNewswire/ -- Today, Abbott (NYSE: ABT) announced new late-breaking data demonstrating use of its FreeStyle Libre system, the world's leading[3] continuous glucose monitoring (CGM) technology, is associated with significant reduction in hemoglobin A1c (HbA1c) levels for people living with type 2 diabetes on either long-acting insulin or non-insulin therapy. These results are similar to outcomes typically seen when adding insulin therapy to treatment regimens,[4] indicating people may be able to manage their glucose levels with CGM technology instead of adding insulin. The real-world data were presented as a late-breaking abstract at the American Diabetes Association (ADA) 80th Scientific Sessions.

In an observational, retrospective study (Abstract 84-LB)1 researchers assessed changes in HbA1c levels in people with type 2 diabetes who were either on long-acting insulin or non-insulin therapy. They analyzed HbA1c levels from baseline to six months and baseline to 12 months after initiating use of the FreeStyle Libre system.

The results demonstrated overall lower HbA1c levels associated with the use of Abbott's technology, specifically a 0.8% drop after six months (from 8.5% to 7.7%) and 0.6% drop after one year of FreeStyle Libre system use (from 8.5% to 7.9%) – clinically significant reductions of average glucose levels over time toward the ADA's recommended A1c goal of 7% for adults with diabetes.[5] Additional notable findings showed:

- The greatest HbA1c decreases occurred among the non-insulin users with type 2 diabetes, including a 0.9% reduction at six months and 0.7% drop after 12 months.
- Among those people with type 2 diabetes on long-acting insulin, HbA1c reductions were 0.6% and 0.5% at six and 12 months, respectively.

"The real-world results are among the first studies that show use of the FreeStyle Libre system can deliver substantial reduction in HbA1c levels for those with type 2 diabetes, whether using insulin or not," said Dr. Eden Miller, D.O., family practice physician at High Lakes Health Care and one of the lead investigators of the study. "These data highlight how use of Abbott's continuous glucose monitor could be game-changing for people beyond intensive insulin users, translating to broader use of the technology to benefit all those living with diabetes, no matter where they are in the spectrum of care."

ADDITIONAL LATE-BREAKERS SHOW REDUCTION IN HBA1C AND HOSPITALIZATIONS

Two additional late-breaking abstracts assessed the impacts of using the FreeStyle Libre system in people living with type 2 diabetes not on intensive insulin therapy (such as bolus insulin). Results demonstrated the following:

- **HbA1c Reduction Associated with a FreeStyle Libre System in People with Type 2 Diabetes Not on Bolus Insulin Therapy**[6] (Abstract 78-LB): A retrospective study found that a prescription for the FreeStyle Libre system in people with type 2 diabetes not on intensive insulin who had poor glucose control was associated with a substantial decrease in HbA1c, with the greatest reduction in those with higher baseline HbA1c levels. Specifically, A1c levels decreased 0.99% after six months in those on long-acting insulin and 1.56% after six months in those not on insulin. For those not using insulin, these results imply that using FreeStyle Libre technology can have a similar impact to using insulin therapy,[4] meaning people could use the FreeStyle Libre system to manage their glucose levels instead of adding insulin.
- **FreeStyle Libre System Use Associated with Reduction in Acute Diabetes Events and All-Cause Hospitalizations in Patients with Type 2 Diabetes Without Bolus Insulin**[2] (Abstract 85-LB): In a retrospective, observational analysis, researchers found that using the FreeStyle Libre system was associated with a sizeable reduction of 30% in acute diabetes events, or complications that can arise from diabetes, and 13% in all-cause hospitalizations among people with type 2 diabetes not on intensive insulin therapy. These late-breaking data suggest significant cost-savings associated with use of the FreeStyle Libre technology, which is priced at a third of the cost of other CGMs,[7] by lowering costly diabetes-related complications and hospitalizations.

"Over time, researchers around the world have generated unparalleled clinical and real-world evidence that reinforce the proven benefits of Abbott's glucose sensing technology," said Mahmood Kazemi, M.D., divisional vice president, global medical and scientific affairs and chief medical officer, Diabetes Care, Abbott. "These new data underscore how our wearable technology provides actionable information to deliver positive outcomes in anyone with diabetes, emphasizing the power of the FreeStyle Libre system to change countless lives among the millions of people with diabetes."

About the FreeStyle Libre System:

Abbott's FreeStyle Libre technology, the #1 sensor-based glucose monitoring system used worldwide,[3] reads glucose levels

through a sensor that can be worn on the back of the upper arm, eliminating the need for fingersticks.[8] The FreeStyle Libre portfolio has changed the lives of more than two million people across 50 countries[9] and has secured partial or full reimbursement in 36 countries, including France, Ireland, Japan, the United Kingdom, and the U.S.

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.

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] Miller, Brandner et al. HbA1c Reduction After Initiation of the FreeStyle Libre System in Type 2 Diabetes Patients on Long-Acting Insulin or Non-Insulin Therapy.

[2] Miller et al. FreeStyle Libre System Use Associated with Reduction in Acute Diabetes Events and All-Cause Hospitalizations in Patients with Type 2 Diabetes Without Bolus Insulin.

[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] Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet. 1998;352(9131):837–853.

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

[6] Wright et al. HbA1c Reduction Associated with a FreeStyle Libre System in People with Type 2 Diabetes Not on Bolus Insulin Therapy.

[7] Based on a comparison of list prices of the FreeStyle Libre portfolio versus competitor 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.

[8] 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.

[9] Data on file, Abbott Diabetes Care.

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For further information: Abbott Media: Molly Cornbleet, (847) 420-9540, Rachael Jarnagin, (224) 360-2146; Abbott Financial: Mike Comilla, (224) 668-1872

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