Abbott Announces Positive Results From Groundbreaking Study Of FreeStyle® Libre System For People With Type 1 Diabetes

- Study shows that FreeStyle® Libre system significantly reduces hypoglycemia in people with Type 1 diabetes without increasing HbA1c, compared to routine self-monitoring of blood glucose (traditional finger sticking)

- Results demonstrate that FreeStyle Libre system safely and successfully replaces routine self-monitoring of blood glucose

NEW ORLEANS, June 13, 2016 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the results of the IMPACT clinical trial, which demonstrated that the FreeStyle® Libre system met its primary endpoint of a reduction in time spent in hypoglycemia (low glucose levels, defined as <70 mg/dL[1]) for people with type 1 diabetes. People in the trial who used Abbott's FreeStyle Libre sensor and reader system spent 38 percent less time in hypoglycemia, as compared to people who managed their glucose with traditional self-monitoring of blood glucose (SMBG) systems (pricking a finger to draw a drop of blood that is added to a test strip inserted into a glucose meter). Data were presented at the American Diabetes Association's 76th Scientific Sessions.

Data from the study also showed that the FreeStyle Libre system reduces all measures of hypoglycemia without increasing HbA1c (an average measurement of glucose levels in the blood over the past 90 days, typically understood to be the 'gold standard' of measuring overall glucose control) versus SMBG, showing that the FreeStyle Libre system can safely and successfully replace the need for routine finger sticks[2] as a tool for managing diabetes.

Traditional self-monitoring of blood glucose among people with both type 1 and type 2 diabetes falls short of U.S., E.U. and other key guidelines that recommend at least 4-8 self-tests per day[3], with the consensus that the more testing per day, the better people have an understanding of their glucose levels and can manage their diabetes accordingly. In actuality, data shows that people test less than three times per day[4]—the biggest obstacle being the pain and hassle of routine finger sticks[5]. But when people with diabetes don't monitor their glucose levels regularly, additional complications including hypoglycemia can become life-threatening.

"Hypoglycemia is the main barrier to attaining optimum glucose control in persons with insulin-treated diabetes. Moreover, hypoglycemic events can not only lead to adverse clinical outcomes including cardiovascular events and death, but they can also incur significant emergency healthcare costs," said Prof. Jan Bolinder, MD, FRCPE, Karolinska Institutet, Stockholm, Sweden, and chief investigator for the IMPACT study. "This clinical trial has proven that patients will test more often when they have an easier and more convenient way to do so utilizing a device like FreeStyle Libre, leading them to ultimately being healthier, which is our goal for our patients."

Empowering patients with data

For the first 14 days of the IMPACT study, the participants wore a FreeStyle Libre sensor but did not have access to their glucose results. During the next period[6], when participants had access to their data via the FreeStyle Libre reader, time spent in hypoglycemia[7] was reduced by 33 percent within two weeks and was sustained by at least this amount (between 33 percent and 42 percent) throughout the study. Time in range (70-180 mg/dL) was increased by one hour per day versus SMBG.

Data from the trial also showed a significant increase in testing frequency with participants scanning their FreeStyle Libre sensors an average of 15 times per day. More scanning led to more access to information about glucose levels, which ultimately led to FreeStyle Libre users being able to take action to significantly reduce their hypoglycemia and hyperglycemia on their own.

"The IMPACT trial confirms the importance of empowering people with the data they need to make their own choices," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "We cannot underestimate the power of knowledge—especially for someone who is managing a chronic condition. Our goal is to help our customers be healthier and live fuller lives, and it's clear from this trial that FreeStyle Libre provides our customers just what they need to do that."

Hypoglycemia and HbA1c

The FreeStyle Libre system has shown that it reduces time spent in hypoglycemia by 38 percent while also significantly reducing nocturnal hypoglycemia (<70 mg/dL; between the hours of 11 p.m. and 6 a.m) by 40 percent. In addition, serious hypoglycemia (<55 mg/dL) was reduced by 50 percent. Throughout the study, results showed FreeStyle Libre users significantly reduced time spent in hypoglycemia without increasing HbA1c, showing that more frequent testing and a complete glycemic profile enables better diabetes management.

Conventional wisdom in diabetes care is that reductions in HbA1c are linked with increasing risk of hypoglycemia[8]—traditionally, there is an inverse relationship between risk of severe hypoglycemia (low glucose levels) and HbA1c reduction (an average number). But in this clinical trial, subjects managed to significantly lower their time spent in hypoglycemia without an increase in their HbA1c levels, shifting a paradigm in the understanding of diabetes treatment and management. In addition, those reductions were achieved rapidly with the first unmasked sensor from the start of the trial and were sustained over the six months of the study through continued use of the FreeStyle Libre system.

About the study

The IMPACT clinical trial is a randomized, controlled six-month trial to evaluate the effectiveness of the FreeStyle Libre system in improving glycemic control for the self-management of type 1 diabetes as compared to self-monitoring of blood glucose

(SMBG). The primary endpoint was a difference in number of hours per day in hypoglycemia (<70 mg/dl) between the group using the FreeStyle Libre system and the group using traditional finger sticks (SMBG) from days 194-208. Two hundred and fifty-two (252) patients over the age of 18 participated in the trial, which took place across 23 sites in Austria, the Netherlands, Spain, Sweden and Germany.

Key findings from the trial include (FreeStyle Libre users versus traditional SMBG):

- 38 percent reduction in time spent in hypoglycemia (<70 mg/dl)
- 40 percent reduction in time spent in nocturnal hypoglycemia at night (11 p.m. to 6 a.m.)
- 50 percent reduction in serious hypoglycemia (<55 mg/dl)
- No increase in HbA1c at six months
- Glucose monitoring increased to an average of 15 scans per day
- Routine finger sticks[2] were nearly eliminated—reduced by 91 percent

About the FreeStyle Libre System
Abbott's FreeStyle Libre system consists of a small, round sensor—approximately the size of two stacked quarters—worn on the back of the upper arm for up to 14 days, which measures glucose every minute in interstitial fluid through a small (5mm long, 0.4mm wide) filament that is inserted just under the skin and held in place with a small adhesive pad. A reader is scanned over the sensor to get a glucose result painlessly[9] in less than one second. Each scan displays a real-time glucose result, an eight hour historical trend and the direction the glucose is heading.

Unlike other continuous glucose monitoring devices (those that measure glucose levels in real-time throughout the day and night), the FreeStyle Libre system is factory calibrated—meaning that it does not require a finger stick test for calibration, where other continuous glucose monitoring systems might require two or more calibrations per day.

In 2014, Abbott launched the FreeStyle Libre system in France, Germany, Italy, the Netherlands, Spain, Sweden and U.K. It is now available in 11 countries in Europe, and recently launched in Australia and Brazil. A professional-use version called FreeStyle Libre Pro utilizes similar technology and is available in India and South Africa.

About Abbott
Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritional and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 74,000 people.

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[1] ADA (American Diabetes Association), CDA (Canadian Diabetes Association) and EMA (European Medicines Agency)

[2] 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.

[3] Schnell O, Alwai H, Battelino T, et al. Consensus statement on self-monitoring of blood glucose in diabetes. A European perspective. Diabetes, Stoffwechsel und Herz, Band 18, 4/2009:3-7

[4] Vincze G, Barner JC, Lopez D. Factors associated with adherence to self-monitoring of blood glucose among persons with diabetes. *Diabetes Educ*. 2004;301(1);112-125.

[5] Wagner J, Malachoff C, Abbott G. Invasiveness as a barrier to self-monitoring of blood glucose in diabetes *Diabetes Technolo Ther*. 2005; 7(4):612-619.

[6] Nominally two weeks between days 15 and 31

[7] Time <70mg/dL

[8] The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. N Engl J Med. 1993;329(14):977-86.

[9] Based on a user study, 100% of patients agree that there is no pain when they check their glucose readings by scanning the FreeStyle Libre sensor.

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