Real-World Data From Abbott's FreeStyle® Libre Show Association Between Higher Frequency Of Glucose Monitoring And Improved Glucose Control For People With Diabetes

- 409 million glucose measurements from more than 50,000 FreeStyle Libre users in Europe show people monitored their glucose levels on average 16 times per day

- 86 million hours of monitoring demonstrate that a higher number of FreeStyle Libre scans is associated with better diabetes outcomes including a reduction in hypoglycemia

PARIS, Feb. 15, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the results of real-world use data[1] showing that people who scan more frequently using Abbott's FreeStyle® Libre system spend less time in hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar) while having improved average glucose levels. According to the data, more than 50,000 people with diabetes using the FreeStyle Libre system checked their glucose levels an average of 16 times per day—which is three times more than the minimum recommended U.S.[2] and European[3] guidelines for testing with the traditional fingerstick technique. The data show that higher rates of scanning with the FreeStyle Libre system were found to be strongly associated with improved glucose control.

"There is now substantial evidence from both real-world usage and clinical studies that reaffirms the powerful impact of FreeStyle Libre," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "FreeStyle Libre is changing how diabetes has been managed for decades, with one simple swipe. Most importantly, we're doing that by empowering patients with the information that they need to take action themselves, helping people living with diabetes live fuller, healthier lives."

Abbott's FreeStyle Libre system consists of a small, round sensor worn on the back of the upper arm for up to 14 days, which measures glucose every minute in interstitial fluid through a small 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[4] in less than one second.

The real-world data findings were presented today at the Advanced Technologies and Treatment for Diabetes (ATTD) congress in Paris. The data show a strong link between real-world use of FreeStyle Libre system and glucose control. The full data set was generated from 50,831 readers, which were used to scan 279,446 sensors. This constituted 409.4 million glucose measurements, 86.4 million monitoring hours and 63.8 million scans – representing more than 50,000 FreeStyle Libre users across the Europe region.

Key findings of the real-world data of the FreeStyle Libre system:

- **More scanning:** Users checked their glucose levels an average of 16.3 scans per day
- **Across the spectrum of scan rates seen in the population, the following trends were observed as scan rates increased:**
    - **Improved HbA1c:** Average glucose level decreased as scan rate increased with estimated HbA1c decreasing from 8.0 to 6.7 percent
    - **Reduction in hypoglycemia**: Time spent below glucose levels of 70, 55 and 45 mg/dL decreased by 15 percent, 40 percent and 49 percent
    - **Reduction in hyperglycemia**: Time above 180 mg/dL decreased from 10.5 to 5.9 hours per day
    - **Increased time in range:** Time in glucose range (70-180 mg/dL) increased from 12.0 to 16.8 hours per day
- **Empowering Patients with Actionable Information**

  According to a published report in *Patient Preference and Adherence*[5] people test with traditional self-monitoring methods (pricking a finger with a lancet to get a blood sample) less than three times per day, which falls short of U.S.[2] and European[3] guidelines that recommend four to eight self-tests per day. People with diabetes cite the biggest obstacle to more frequent monitoring is the pain and hassle of routine fingersticks[5].

  But when people with diabetes don't have a clear picture of their glucose levels from regular monitoring, complications such as hypoglycemia can become life-threatening and require hospitalization, which can lead to a significant increase in healthcare costs.

  Abbott's FreeStyle Libre system, which was introduced inEurope in 2014, removes the need for routine fingersticks[6], [7] — and the pain and hassles that come along with them[8]. In addition, FreeStyle Libre system is factory calibrated —meaning that it does not require a fingerstick test for calibration (a test requiring a blood sample to reset a system's accuracy) unlike other continuous glucose monitoring systems, which require two or more fingersticks per day to remain accurate.

  "My experience with FreeStyle Libre through daily clinical practice and research studies has been very positive," says Ramzi Ajjan, M.D., University ofLeeds, U.K. "Patients report that the system helped them gain a better understanding of their glycaemia by enabling multiple daily glucose checks discreetly and conveniently. The system's painless nature of glucose testing are praised by patients with one commenting to me, 'you saved my fingers.' The real-world data further confirms that patients are checking glucose more frequently, up to 16 times per day on average, which is

cumbersome to maintain with the conventional fingerstick method. With comprehensive glucose data, patients now have access to more meaningful information key for optimizing their glycaemia control."

Real-World Usage Supports Randomized Controlled Data of FreeStyle Libre
The new real-world data presented at ATTD further support the conclusions of the randomized controlled clinical studies conducted by Abbott with the FreeStyle Libre system including the IMPACT study[9] published in *The Lancet* in September 2016.

Key findings of the IMPACT trial included (FreeStyle Libre users versus traditional SMBG):

In 2014, Abbott launched the FreeStyle Libre system in several countries inEurope. Currently, FreeStyle Libre system is available in more than 30 countries around the globe and is being used by more than 250,000 people living with diabetes. In the U.S., the FreeStyle Libre system is currently under review by the U.S. Food and Drug Administration[10].

About the Data
De-identified data was collected over a period of 18 months when FreeStyle Libre readers were connected to the PC-based software with an active internet connection. All information was aggregated. No personal data was utilized or shared.

About Abbott's FreeStyle Libre System
Abbott's FreeStyle Libre system consists of a small, round sensor—approximately the size of two stacked U.S. 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[4] in less than one second. Each scan displays a real-time glucose result, a historical trend and the direction the glucose is heading.

The FreeStyle Libre system generates an Ambulatory Glucose Profile (AGP) that provides a visual snapshot of glucose levels, trends and patterns over time.

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, 94,000 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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[1] Data on file. Dunn T, Xu Y, Hayter G; Evidence of a Strong Association Between Frequency of Flash Glucose Monitoring and Glucose Control Measures During Real-World Usage

[2] American Diabetes Association Diabetes Care 2017 Jan; 40(Supplement 1): S48-S56. https://doi.org/10.2337/dc17-S009; http://care.diabetesjournals.org/content/40/Supplement_1/S48

[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] Data on file. 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.

[5] Ong, W.M.; Chua, S.S.; Ng, C.J. (2014) *Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: a qualitative study.* Patient Preference and Adherence, 8. pp. 237-246.

[6] 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.

[7] Bailey, Bode, Christiansen, Klaff, and Alva, (2015). The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System Diabetes Tech Thearputics 17(11), 787-793.DOI: 10.1089/dia.2014.0378

[8] 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.

[9] Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kroger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial [published online September 12, 2016]. Lancet. 2016

[10] Pending FDA approval. Not available for sale in the United States

SOURCE Abbott

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  - Glucose monitoring increased to an average of 15 scans per day
  - 38 percent reduction in time spent in hypoglycemia (<70 mg/dl)
  - 50 percent reduction in serious hypoglycemia (<55 mg/dl)
  - 40 percent reduction in time spent in nocturnal hypoglycemia at night (11 p.m. to 6 a.m.)
  - No increase in HbA1c at six months

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