Abbott Receives FDA Approval For The FreeStyle Libre Pro™ System, A Revolutionary Diabetes Sensing Technology For Healthcare Professionals To Use With Their Patients

- Freestyle Libre Pro is a continuous glucose monitoring (CGM) system designed to provide a clear, visual snapshot of a patient's glucose levels, trends and patterns for up to 14 days

- Requires no fingersticks to calibrate the system -- an advantage over other professional use CGM devices

- Significantly lower cost than other professional CGM systems

- Consumer version of the technology, FreeStyle Libre™, is currently under review by the U.S. Food and Drug Administration

ABBOTT PARK, Ill., Sept. 28, 2016 — Abbott today announced that the U.S. Food and Drug Administration (FDA) has approved the company's FreeStyle Libre Pro system, a revolutionary continuous glucose monitoring (CGM) system for healthcare professionals to use with their patients with diabetes.

FreeStyle Libre Pro system is designed to empower healthcare professionals to provide better diabetes management for diabetes patients. The system provides healthcare professionals with a visual snapshot of glucose data, known as the Ambulatory Glucose Profile (AGP), giving a more simplified and clear overview of not only glucose levels, but also patterns and trends within those levels. This valuable information helps healthcare professionals make better, customized treatment decisions for their patients – and for a significantly lower cost than other professional CGM products available[i].

On nearly a daily basis, Eugene E. Wright, Jr., M.D. of Duke Southern Regional Area Health Education Center in Fayetteville, N.C., finds it challenging to effectively treat his patients with diabetes when it comes to decisions around insulin, nutrition and medication. "My patients are often out of range, due to inconsistent self-monitoring and insufficient data from traditional glucose meters that are unable to provide a full view of their glucose levels."

"FreeStyle Libre Pro transforms how doctors assess their patients' diabetes," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "This novel technology provides a solution to the ongoing challenge of the need for complete and dependable glucose data. This data is imperative for not only the doctor, but also for the patient to help them achieve optimal health."

The FreeStyle Libre Pro System—How it Works

Abbott's FreeStyle Libre Pro system is applied to patients by healthcare professionals in a clinic setting. A healthcare professional applies a small, round sensor on the back of the patient's upper arm. The water-resistant[ii] and disposable sensor is held in place with a self-adhesive pad and remains on the back of the arm for up to 14 days, requiring no patient interaction with the device or the need for the patient to draw blood via a fingerstick to calibrate the sensor.

The sensor continuously measures glucose in interstitial fluid through a small (5mm long, 0.4mm wide) filament that is inserted just under the skin. It records glucose levels every 15 minutes, capturing up to 1340 glucose results for up to 14 days, giving the treating doctor comprehensive data for a complete glycemic profile of their patient. After 14 days, the patient returns to the doctor's office, where the doctor uses a FreeStyle Libre Pro reader to scan the sensor and download the 14-days' worth of glucose results that are stored in the sensor – in as little as five seconds.

Abbott's FreeStyle Libre Pro system has a number of key advantages compared to other professional CGM systems, including:

- **Convenient for both the doctor and the patient.** With the FreeStyle Libre Pro system there is no requirement for fingerstick calibration so patients do not need to be trained by their healthcare professional on calibration. After the sensor is applied to the patient, there is no requirement for the patient to interact with the system.
- **Provides reliable glucose data.** Healthcare professionals receive up to 14 days of continuous glucose data based on uninterrupted, normal daily routines of their patients.
- **Reduce equipment costs, maintenance and time.** FreeStyle Libre Pro system costs significantly less than other professional CGM products on the market.[i] The doctor’s office only needs to purchase one FreeStyle Libre Pro reader for multiple patients without having to spend on extra recorders, receivers and transmitters, or devote time to routine disinfecting or recharging patient use components. In addition to the glucose sensor, other professional CGM systems require reusable hardware components, such as receivers, transmitters, and recorders that must go home with each patient to perform the professional CGM assessment.

Ambulatory Glucose Profile—a Complete Glycemic Profile

The FreeStyle Libre Pro system provides patients and their physicians with an Ambulatory Glucose Profile (AGP), a report developed by the International Diabetes Center that is presented in a single, user-friendly, visual chart providing healthcare professionals a complete glycemic view of their patients' glucose trends for up to 14 days.

The AGP report helps identify when a patient is out of glucose range, and provides hypoglycemic and hyperglycemic trends and patterns. These insights help facilitate more meaningful discussions between a doctor and the patient.

Dr. Wright added, "This technology is groundbreaking because continuous glucose monitoring systems for professional use

have been long considered a niche, cumbersome, and expensive technology for mostly Type 1 patients. The FreeStyle Libre Pro system changes this paradigm not only because of the unique technology but because it doesn't require fingerstick calibration, is easier to use, more affordable, and is more accessible to people with diabetes."

The FreeStyle Libre Pro system is part of Abbott's FreeStyle family of products including the sensing technology for consumers, the FreeStyle Libre system.

Abbott recently submitted the consumer version of the FreeStyle Libre system for review by the U.S. Food and Drug Administration. The consumer version of the FreeStyle Libre system is designed to be a continuous glucose monitoring system that does not require fingerstick calibration, and measures glucose levels through a small sensor on the back of the upper arm for up to 14 days. Patients can self-monitor their glucose levels by scanning a reader over the sensor as often as desired to get a reading.

About Diabetes and Diabetes Monitoring

According to the International Diabetes Federation, the U.S. has one of the highest prevalence rates for diabetes, with 29.1 million people (or 9 percent of the U.S. population) who have diabetes. A recent survey of 1,527 people with Type 2 diabetes found that 40 percent do not test glucose levels as frequently as recommended by their doctors. Reasons for testing less often than recommended include expense of testing strips (31 percent), dislike of pricking fingers to draw blood for testing (29 percent), and forgetting to test because they feel fine (26 percent).[iii]

Traditionally, continuous glucose monitoring devices have primarily been used by people with Type 1 diabetes whom are required to take insulin. However, both Type 1 and Type 2 diabetes patients can experience conditions such as hypoglycemia (low blood sugar) which can be life-threatening, especially when not detected. Because the FreeStyle Libre Pro system provides rich, insightful data, patterns that might otherwise be missed—such as nighttime hypoglycemia—glucose levels excursions can be detected and therefore managed.

Abbott's FreeStyle Libre Pro system will be available to U.S. healthcare professionals in the coming weeks. For more information, please go to www.FreeStyleLibrePro.us.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The System is intended for use by health care professionals and requires a prescription. Readings from the FreeStyle Libre Pro Sensor are only made available to patients through consultation with a health care professional. The System does not require user calibration with blood glucose values. The FreeStyle Libre Pro System aids in the detection of glucose level excursions above or below the desired range, facilitating therapy adjustments. Interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should be based on the trends and patterns analyzed through time using the reports available.

IMPORTANT: The device may inaccurately indicate hypoglycemia. The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81-160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use.

CONTRAINDICATIONS: The FreeStyle Libre Pro Flash Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device to detect trends and track patterns in the user’s glucose values during the wear period.

WARNING: The FreeStyle Libre Pro Flash Glucose Monitoring System contains small parts that may be dangerous if swallowed.

CAUTION:

- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If your patient notices significant skin irritation around or under their Sensor, they should remove the Sensor and stop using the FreeStyle Libre Pro System. Follow your facility’s procedures for handling skin reactions.

WARNINGS/LIMITATIONS

- Review all product information before use.
- Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.
- Severe dehydration and excessive water loss may cause inaccurate results.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose

readings and infection. Not suitable for re-sterilization. Further exposure to irradiation may cause inaccurate results.

- Interfering Substances: Taking ascorbic acid (vitamin C) while wearing the Sensor may falsely raise Sensor glucose readings. Taking salicylic acid (used in some pain relievers such as aspirin and some skin care products) may slightly lower Sensor glucose readings. The level of inaccuracy depends on the amount of the interfering substance active in the body. Test results did not indicate interference for methyldopa (used in some drugs to treat high blood pressure) or tolbutamide (infrequently used in some drugs to treat diabetes in the US) at maximum circulating levels. However, concentrations of potential interferents in interstitial fluid are unknown compared to circulating blood. Taking medications with acetaminophen (such as Tylenol and some cold medicines) while wearing the Sensor may falsely raise Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in the body and may be different for each person.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.
- The Reader should be cleaned between patients.
- If a Sensor breaks inside a patient, remove with tweezers, treat any medical complications and call Customer Service.
- Use of the System is not recommended in the critically ill population since performance is unknown due to different conditions and medications.
- Sensor placement is not approved for sites other than the back of the arm. If placed in other areas, the Sensor may not function properly.
- If the Sensor Kit package or contents or the Reader appear to be damaged, do not use as there may be a risk of electric shock, no results, and/or infection.
- Store the Sensor Kit between 39°F-77°F. While you don't need to keep the Sensor Kit in a refrigerator, you can as long as the refrigerator is between 39°F-77°F.
- Store the Sensor Kit between 10-90% non-condensing humidity.
- The System does not provide real-time results. Patients need to rely on blood glucose readings for monitoring glucose during System use.
- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Clean the application site and ensure that it is dry prior to Sensor insertion. This helps the Sensor stay attached to the body.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.
- The Sensor should not be worn more than 14 days. Readings are not obtained after 14 days.
- The Sensor should be removed prior to exposing it to an X-ray machine. The effect of X-rays on the performance of the system has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device to detect trends and track patterns in the user's glucose values during the wear period.
- The FreeStyle Libre Pro Flash Glucose Monitoring System has not been evaluated for use in pregnant women, persons on dialysis, or people less than 18 years of age.

About Abbott:
At Abbott, we're committed to helping you live your 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, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

Connect with us at www.abbott.com, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

[i] Dexcom and Medtronic Professional CGM Order Forms, 2015

[ii] Sensor is water-resistant in up to 1 metre of water. Do not immerse longer than 30 minutes.

[iii] These are findings from an Ipsos poll conductedAugust 19-September 1, 2016. For the survey, a sample of roughly 2,679 adults age 18+ from the continental U.S., Alaska and Hawaii was interviewed online in English. The sample includes 1,152 adults with Type I diabetes and 1,527 adults with Type 2 diabetes. The poll also has a credibility interval plus or minus 3.3 percentage points for those with Type 1 diabetes and plus or minus 2.9 percentage points for those with Type 2 diabetes. Data on file.

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