Medtronic News

Medtronic Receives FDA Approval for Guardian Connect Continuous Glucose Monitoring (CGM) System for People Living with Diabetes

'Smart' CGM System Provides Predictive Alerts for Dangerous Sensor Glucose Levels; Exclusive Access to Sugar.IQ Assistant with Watson Offers More Proactive Diabetes Management

DUBLIN - March 12, 2018 - Medtronic plc (NYSE:MDT), the global leader in medical technology, services and solutions, today announced it received U.S. Food and Drug Administration (FDA) approval for its Guardian(TM) Connect continuous glucose monitoring (CGM) system, for people with diabetes ages 14 to 75 years. The Guardian Connect system is the first smart standalone CGM system1 to help people with diabetes stay ahead of high and low glucose events. The Guardian Connect system empowers people using multiple daily injections (MDI) to more proactively manage their diabetes.

Featuring our latest predictive algorithms in diabetes care, the Guardian Connect system is the only standalone CGM system that can alert patients of potential high or low glucose events up to 60 minutes in advance. Using Guardian(TM) Sensor 3, the most advanced glucose sensor from Medtronic and the only sensor trusted to power a hybrid closed loop system, the Guardian Connect system was proven in a clinical study to accurately alert patients of 98.5 percent of hypoglycemic events2. Care partners can use the system to stay more informed about their loved ones with diabetes as well by tracking glucose in real-time or receiving text alerts.

People using the Guardian Connect system will also have exclusive access to the groundbreaking Sugar.IQ(TM) smart diabetes assistant, empowering them to further address the daily challenges of diabetes. With artificial intelligence technology from IBM Watson Health, the Sugar.IQ assistant continually analyzes how an individual's glucose levels respond to their food intake, insulin dosages, daily routines, and other factors3. Together with the Guardian Connect system, the Sugar.IQ assistant can turn difficult-to-determine patterns into personalized, actionable insights that help people with diabetes keep glucose levels in their target range.

"Despite proven benefits and advances in technology, only a minority of insulin-using people with diabetes currently use continuous glucose monitors (CGM)" said Dr. Timothy Bailey, director of the AMCR Institute and clinical associate professor, University of California, San Diego. "Newer sensors paired with intelligent algorithms that help to both predict and understand glucose excursions, particularly hypoglycemia, will make diabetes safer and more comprehensible for people who inject insulin. Greater utilization of smarter CGM systems promises to allow our patients to achieve more glycemic time-in-range and to further reduce the risk of hypoglycemia."

"The FDA approval of the Guardian Connect system fills a key gap that exists in diabetes treatment today - how to predict dangerous glucose highs and lows so they can be potentially avoided," said Annette Brüls, president, Diabetes Service and Solutions at Medtronic. "With predictive alerts and the Sugar.IQ assistant, the Guardian(TM) Connect system enables people to proactively manage their diabetes, so they can focus on living their life, not constantly worrying about their glucose levels."

The Guardian Connect system will be available in the first quarter of Medtronic's fiscal year 2019 (May 2018 - July 2018) for people with diabetes who are looking to take on a more proactive role in managing their diabetes.

About Continuous Glucose Monitoring (CGM)
A CGM system provides continuous, real-time glucose value and trend information about glucose levels for people with diabetes. In addition, a smart CGM system predicts future high and low glucose events and provides access to additional algorithms and insights that can inform users of clinically relevant glucose patterns. This allows for appropriate intervention (after verifying with a blood fingerstick test) to mitigate hyperglycemia (high blood glucose) or hypoglycemia (low blood

glucose), increasing the patient's time in the optimal glucose target range. To use a CGM system, the person with diabetes inserts a tiny sensor beneath the skin, in the abdomen or upper arm. The sensor, which measures glucose levels from the interstitial fluid under the skin, is attached to a transmitter that sends readings to an app, wearable monitor or insulin pump every five minutes. Alerts can be customized to notify patients up to 60 minutes before they reach personal preset low or high sensor glucose limits. CGM provides a more complete picture because it reveals high and low glucose levels that periodic blood fingerstick testing might miss.

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)
Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1 Smart CGM predicts future high and low sensor glucose events and provides access to additional algorithms and insights that can inform users of clinically relevant glucose patterns.

2 Guardian Connect system Instructions for Use (IFU). With a sensor glucose limit of 70 mg/dL, with calibration every 12 hours, both predictive and threshold alerts "On," within 30 minutes; abdomen sensor insertion. The correct detection rate for arm inserted sensor is 96.7 percent; with the same settings and conditions.

3 Based on information provided by the user.

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