Medtronic News

Medtronic Begins Pivotal Study of First Predictive Low Glucose Management Technology for People with Diabetes

In-Clinic Study Marks Critical Step Toward an Artificial Pancreas and Key Milestone Toward U.S. Commercialization

MINNEAPOLIS - October 14, 2014 - Medtronic, Inc. (NYSE:MDT) today announced that the first patients have been enrolled in an investigational device exemption (IDE) study of its breakthrough Predictive Low Glucose Management (PLGM) technology, marking a critical step toward development of an artificial pancreas in the U.S. market. The trial will evaluate the safety of its next-generation integrated insulin pump and continuous glucose monitoring (CGM) system, which automatically stops insulin delivery when the sensor measures a glucose level predicted to approach the lowest tolerable limit, and then resumes insulin delivery after those glucose levels recover. The technology is designed to help people with diabetes better manage the challenges of hypoglycemia (low blood sugar) and rebound hyperglycemia (high blood sugar) inherent in external insulin therapy use.

"Safely managing hypoglycemia without causing a rebound hyperglycemic episode is a key challenge in managing diabetes," said Ronald Brazg, M.D., FACE clinical assistant professor of medicine, Division of Metabolism and Endocrinology at the University of Washington, and director of Rainier Clinical Research Center, which is one of the participating centers for this trial. "This important study leads the industry-wide effort to close the diabetes treatment loop with tools that help achieve better glycemic control."

A total of up to 84 subjects will be enrolled at up to eight investigational centers across the United States. The Medtronic system being studied includes a fourth generation sensor with new intelligent sensor diagnostics, which is 80% smaller than the Enlite sensor currently available in the U.S. market, and a new MiniMed insulin pump design. The objective of the study is to evaluate the safety of the PLGM algorithm with the new sensor as well as the algorithm's ability to prevent hypoglycemia. Hypoglycemia is a common occurrence and concern in diabetes management and can result in confusion, unresponsiveness and - in severe cases - even death.

PLGM technology builds upon Medtronic's already available Threshold Suspend feature, the only technology available in the U.S. that can automatically stop insulin delivery when sensor glucose values reach a preset level and when the patient doesn't respond to the Threshold Suspend alarm. PLGM takes the interaction with the insulin pump a step further by automatically stopping insulin delivery when the sensor glucose level is predicted to approach a low limit, and then resuming insulin delivery after those glucose levels recover.

"This study marks yet another important milestone toward the goal of an artificial pancreas. As we continue to lead the world with advances in insulin delivery, sensor technology and algorithms, we will be more able to help people with diabetes enjoy greater freedom and experience better health," said Alejandro Galindo, vice president and general manager of the Intensive Insulin Management business at Medtronic.

The IDE study on PLGM technology demonstrates the next step toward Medtronic's ultimate goal of developing an automated artificial pancreas - a system that would automatically adjust insulin levels based on sensor glucose levels with very little interaction from the patient. Previous milestones include:

- 2006: Medtronic introduced the world's first integrated insulin pump and continuous glucose monitor.
- 2009: Medtronic introduced the world's first integrated insulin pump with Low Glucose Suspend technology in Europe
- 2013: Medtronic introduced the MiniMed 530G with Enlite, which features Threshold Suspend technology, in the U.S.

For more details, including enrollment information, please visit[clinicaltrials.gov](www.clinicaltrials.gov/ct2/results?) (www.clinicaltrials.gov/ct2/results?

term=NCT02130284)

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, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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Contacts:
Amanda Sheldon
Public Relations
+1-818-576-4826

Jeff Warren
Investor Relations
+1-763-505-2696

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