Medtronic News

Medtronic Receives IDE Approval to Conduct ASPIRE In-Home Study of First Insulin Pump with Low Glucose Suspend for US Market

A Critical Step Toward the Development of an Artificial Pancreas, Low Glucose Suspend Aims to Reduce Hypoglycemia

MINNEAPOLIS, Oct 28, 2011 (BUSINESS WIRE) --

In our continued commitment to develop an artificial pancreas, Medtronic, Inc. (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval of its Investigational Device Exemption (IDE) to conduct a pivotal in-home clinical trial protocol for the ASPIRE study of the MiniMed Paradigm(R) System featuring Low Glucose Suspend (LGS) automation. FDA approval of the IDE makes Medtronic's ASPIRE study the first in-home pivotal trial of a closed loop system for Type 1 diabetes management.

"This study leads an industry-wide effort to close the diabetes treatment loop by tackling the important challenge of reducing the risk of hypoglycemia even when a person is asleep or unable to react," said David Klonoff, Medical Director of the Diabetes Research Institute at Mills-Peninsula Health Services. "The new Low Glucose Suspend integrated system is designed to help improve patients' ability to manage nocturnal hypoglycemia, which can be one of the most frightening aspects of living with Type 1 diabetes. Until now, we have never had a therapy designed to automatically intervene when blood glucose becomes severely low."

"FDA approval of the ASPIRE in-home study is an important milestone toward bringing Low Glucose Suspend technology to the U.S. market," said Dr. Francine Kaufman, Chief Medical Officer and Vice President of Global Clinical Affairs for the Diabetes business of Medtronic. "It's also a critical step toward our ultimate goal -- the development of an artificial pancreas. We believe this innovation has the potential to provide patients with added protection by lowering the risks associated with nocturnal hypoglycemia."

This is the second phase of the ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) study, following the completion of the in-patient clinical study. ASPIRE is a multi-center, randomized, pivotal in-home study being conducted at multiple investigational centers to determine the safety and efficacy of the Low Glucose Suspend feature in the sensor-augmented MiniMed Paradigm insulin pump. Medtronic's newest continuous glucose sensor, the Enlite(TM) sensor, will be tested as part of the overall system.

ASPIRE will compare hypoglycemic events in a treatment arm with the LGS ON to a control arm that has the LGS OFF in the actual use environment and by the intended use population with Type 1 diabetes. The first study objective is to demonstrate that home use of LGS is safe and is not associated with glycemic deterioration, as measured by a change in HbA1C. The second study objective is to demonstrate that home use of LGS is associated with a reduction in nocturnal hypoglycemia when patients fail to respond. Hypoglycemia is a common occurrence and concern in diabetes management and can result in confusion, unresponsiveness and -- in severe cases -- even death.

"FDA review of the ASPIRE IDE application was conducted through an interactive review process that involved frequent communication with the FDA review team, allowing issues to be resolved quickly and avoiding any unnecessary delays during the review. We appreciate the valuable input provided by members of the FDA's Artificial Pancreas Working Group," added Dr. Kaufman.

Medtronic's MiniMed Paradigm(R) REAL-TimeRevel(TM) System, currently available in the United States, is the second generation of the only insulin pump integrated with continuous glucose monitoring (CGM) cleared by the FDA. With the addition of LGS, Medtronic has designed a first-of-its-kind semi-closed loop system that not only features insulin delivery and CGM, but

also advanced software algorithms that enable the Low Glucose Suspend automation. Low Glucose Suspend works by automatically suspending basal insulin delivery temporarily if glucose levels become too low as defined by the patient and his or her healthcare provider. It is a feature available commercially in Medtronic's Paradigm(R) Veo(TM) System in more than 50 countries outside of the United States. The CGM-integrated system and Low Glucose Suspend automation are the first key steps towards the creation of an artificial pancreas.

Hypoglycemia can be one of the most frightening aspects of living with diabetes. Research has indicated that, on average, a person with diabetes will experience more than one low blood glucose event every two weeks. In addition, each year nearly one in 14 people with insulin-treated diabetes will experience one or more episodes of severe hypoglycemia.1

About the Diabetes Business at Medtronic
The Diabetes business at Medtronic (www.medtronicdiabetes.com) is the world leader in advanced diabetes management solutions, including integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, as well as world-class, 24/7 expert consumer and professional service and support.

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.

References
1. Leese GP, Wang J et al. Frequency of severe hypoglycemia requiring emergency treatment in Type 1 and Type 2 diabetes. *Diabetes Care* 26:1176-1180, 2003.

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