Medtronic News

Medtronic Begins Enrollment in ASPIRE Pivotal Study of Low Glucose Suspend Integrated System

Semi-Closed Loop System Designed to Reduce Severity and Duration of Hypoglycemia

MINNEAPOLIS, Jun 25, 2010 (BUSINESS WIRE) --Demonstrating its dedication to close the loop for diabetes management, Medtronic, Inc. (NYSE:MDT) today announced that the first patient has been enrolled as part of the ASPIRE study of the MiniMed Paradigm x54 System featuring Low Glucose Suspend automation. Low Glucose Suspend works by automatically suspending insulin delivery temporarily if blood glucose levels become too low as defined by the patient and his or her healthcare provider and is a feature available commercially in Medtronic's Paradigm(R) Veo(TM) System in more than 35 countries outside of United States.

ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) is a multi-center, randomized, investigational device exemption (IDE) study designed to assess the efficacy of the MiniMed Paradigm x54 System Low Glucose Suspend function in reducing the duration and severity of hypoglycemia (low blood glucose). Hypoglycemia is a common occurrence and concern in diabetes management and can result in confusion, unresponsiveness and - in rare cases - even death.

"Hypoglycemia is the greatest fear and biggest hurdle in achieving better glucose control in patients with diabetes. Until now we have never had a therapy designed to automatically intervene when blood glucose becomes dangerously low," said Satish K. Garg M.D., professor of Medicine and Pediatrics, Barbara Davis Center for Childhood Diabetes. "The new Low Glucose Suspend integrated system is intended to close the treatment loop, ultimately reducing the risk of hypoglycemia even when a person is asleep or unable to react."

Medtronic's MiniMed Paradigm(R) REAL-TimeRevel(TM) system is the second generation of the only integrated insulin pump with continuous glucose monitoring system cleared by the U.S. Food and Drug Administration (FDA). With the MiniMed Paradigm x54, Medtronic has designed a first-of-its-kind semi-closed loop system that not only features insulin delivery and CGM sensors, but also advanced software algorithms that enable the Low Glucose Suspend automation. The integrated system and low glucose suspend automation are the first key steps towards the creation of an artificial pancreas.

"The commencement of the ASPIRE study is the result of extensive interaction between Medtronic and the FDA to identify the clinical data required for FDA approval of our Low Glucose Suspend integrated system, an innovation we believe has the potential to transform the way diabetes is managed," said Katie Szyman, president of the Diabetes business and senior vice president at Medtronic. "Building on our commercial success with the Veo in Europe, we look forward to the opportunity of bringing yet another new and important 'first' to U.S. patients for whom hypoglycemia is a significant and constant concern."

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 The landmark Diabetes Control and Complications Trial showed that severe hypoglycemia is more common in adolescents than in adults, and hypoglycemia has been shown to be a risk factor for reduced cognitive functioning among the pediatric patient population.2,3

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

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SOURCE: Medtronic, Inc.

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