Medtronic News

Study of Next Step Toward Artificial Pancreas from Medtronic Meets Efficacy Endpoints

World's First Insulin Pump with Low Glucose Suspend Showed Reduces Time Spent in Low Threshold Range

MINNEAPOLIS--(BUSINESS WIRE)--Feb. 29, 2012-- In the next step toward the development of an artificial pancreas, Medtronic, Inc. (NYSE:MDT) today announced that the results of the in-clinic ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) study have been published online and in the March edition of *Diabetes Technology & Therapeutics*. The ASPIRE study met its efficacy endpoints and showed a 19% reduction in time spent below the low glucose threshold in patients using the MiniMed Paradigm System featuring Low Glucose Suspend (LGS) automation, compared to conventional pump therapy. The LGS feature of the integrated insulin pump and continuous glucose monitor works by automatically suspending insulin delivery if the sensor glucose value is equal to or below the low threshold value. The Paradigm System is commercially available outside the United States but limited to investigational use in the U.S.

"Until now we have never had a therapy designed to automatically intervene when blood glucose becomes dangerously low, which is the greatest fear and biggest challenge in achieving better glucose control in patients with diabetes," said Satish K. Garg, M.D., professor of Medicine and Pediatrics, Barbara Davis Center for Childhood Diabetes. "Therapies that help people with diabetes stay within normal range are important and we look forward to continue advancements in this area. It makes sense to stop insulin delivery when a low glucose threshold is met and that is how LGS is designed."

Hypoglycemia can be one of the most frightening aspects of living with diabetes because it can result in confusion, unresponsiveness, loss of consciousness, coma and – in rare cases – even death. 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 ASPIRE study showed that people with diabetes using the MiniMed Paradigm System featuring Low Glucose Suspend (LGS) automation spent less time below 70 mg/dL – the low glucose value at which insulin was suspended. In addition, the study group's average drop in blood glucose values remained higher compared to patients using conventional insulin pumps (mean nadir YSI 59.5 – 5.72 vs. 57.6 – 5.69 mg/dL, p=0.015). In addition, the LGS suspension did not result in rebound hyperglycemia (high blood sugar). Over half of the glucose values with LGS-ON at the end of observation were in the normal range (70-180 mg/dL) and none were in the hyperglycemic range (>250 mg/dL).

"Achieving the endpoints of the in-clinic ASPIRE study is an important milestone towardFDA approval and 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. "We are excited about this first step and are committed to advancing the insulin delivery, sensor technology, and closed loop algorithms to commercialize an artificial pancreas."

ASPIRE, sponsored by Medtronic, is a multi-center, randomized, investigational device exemption (IDE) study designed to assess the efficacy of the MiniMed Paradigm System Low Glucose Suspend function in reducing the duration and severity of hypoglycemia. Subjects fasted overnight and exercised until their venous glucose value was &70 mg/dL. The in-home phase of ASPIRE is now enrolling.

Medtronic's MiniMed Paradigm® REAL-Time Revel™ System, currently available inthe United States, is the second generation of the only insulin pump integrated with continuous glucose monitoring (CGM) approved by the FDA. With the addition of LGS, Medtronic has designed a first-of-its-kind semi-closed loop system, which is available commercially in the Paradigm® Veo™ System in more than 50 countries outside of the United States.

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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Medtronic, Inc.
Amanda Sheldon, 818-576-4826
Public Relations
Jeff Warren, 763-505-2696
Investor Relations

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