Medtronic News

Research Presented at ADA Adds to the Clinical Evidence for Medtronic's Sensor-Augmented Insulin Pump Therapy

STAR 3 Continuation Data, Low Glucose Suspend and Patient Reported Outcomes Highlighted at American Diabetes Association's 71st Scientific Sessions

SAN DIEGO, Jun 25, 2011 (BUSINESS WIRE) --

Research presented at the American Diabetes Association's 71st Scientific Sessions (ADA) this week adds to the clinical evidence for Medtronic's sensor-augmented insulin pump therapy for improved glucose control for people with type 1 diabetes. Medtronic has the only FDA-approved sensor-augmented insulin pump (an insulin pump that integrates continuous glucose monitoring into one device).

"Extensive clinical research has proven that our advancements in insulin delivery and continuous glucose monitoring technologies have improved outcomes for people with diabetes," said Francine Kaufman, M.D., chief medical officer and vice president, global medical, clinical & health affairs at Medtronic. "We are committed to building upon this evidence to expand access to care around the world and to advancing innovation that will lead to an artificial pancreas system."

Key Presentations on June 26 and June 27 Will Include:

Sensor-Augmented Pump Therapy for A1C Reduction (STAR 3) Study: Results from the 6-Month Continuation Phase

Presidential Poster Session - June 26, 2011, 6:45-8pm, Hall B

Dr. Richard Bergenstalwill present data from the continuation phase of the landmark STAR 3 trial. The research shows mean A1C levels for the 204 participants who continued on sensor-augmented pump therapy remained reduced. In addition, for the 190 participants in the control group who then switched from multiple daily insulin injections to sensor-augmented pump therapy in the continuation phase, mean A1C levels dropped from 8.1 to 7.6 ($p<0.01$) after pump training and three months of use, and were sustained for all six months of continuation phase.

Patient-Reported Outcomes in the Sensor-Augmented Pump Therapy for A1C Reduction 3 (STAR 3) Trial

Oral Session - June 27, 2011, 2:30-2:45pm, Room 23

Dr. Richard Rubin reports on patient reported outcomes of sensor-augmented insulin pump therapy (SAPT) compared to multiple daily insulin injections in the STAR 3 trial. Advantages identified for SAPT included treatment satisfaction in adult patients, child patients, and children's caregivers, and for hypoglycemia fear in adult patients and children's caregivers.

Characterization of the Low Glucose Suspend Feature of the Medtronic MiniMed Paradigm Veo Insulin Pump System and Events Preceding Its Activation

Audio Poster - June 27, 2011, 12-1pm, Hall B

Dr. Francine Kaufman will present an analysis of data from users of the Paradigm Veo insulin pump with low glucose suspend (LGS) , a feature that allows for automatic suspension of insulin delivery at a pre-specified low glucose value. The Paradigm Veo is not approved for use in the United States. The analysis showed that the LGS feature reduced the time spent in hypoglycemia (low blood sugar) and did not increase hyperglycemia (high blood sugar). Out of 278 subjects with three months' continuous sensor wear (during which LGS was on for 92 percent of the patient-days), the percent of sensor glucose values less than 50 mg/dl was 0.92 percent with LGS on and 1.33 percent with LGS off ($P<0.001$). The percent of sensor glucose

values greater than 240 mg/dl was 11.28 percent with LGS on and 11.65 percent with LGS off (P=0.023). In the 3-hour time period prior to a low glucose suspend activation, patients commonly had hyperglycemia, took an insulin bolus for food and/or administered a large manual bolus.

"In addition to providing better clinical outcomes, advance diabetes technology should ideally benefit the patient's quality of life and satisfaction with therapy," said Richard R. Rubin, Ph.D. "The patient reported outcomes of STAR 3 demonstrated that sensor-augmented pump therapy provides advantages compared to multiple daily injection, especially for treatment satisfaction, and for fear of hypoglycemia which can be one of the hardest aspects of managing diabetes for adults and caregivers."

For more information about the research presented at these sessions and Medtronic's integrated diabetes management system, please visit booth #515.

About STAR 3

In the longest and largest randomized, controlled study of sensor-augmented insulin pump therapy in type 1 diabetes, adult and pediatric patients using the Medtronic MiniMed Paradigm(R) REAL-Time System achieved better glucose control without an increase in hypoglycemia compared to multiple daily insulin injections (MDI), the most common approach to care today . Twelve-month data presented at ADA in 2010 showed patients (adults, teens and children) on sensor-augmented insulin pump therapy demonstrated a reduction in mean A1C levels that was four times greater than the MDI group (from a baseline of 8.3 percent to 7.5 percent in the sensor-augmented pump therapy group, compared to only 8.3 percent to 8.1 percent in the MDI group (p<.001)).

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.

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SOURCE: Medtronic, Inc.

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

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