Medtronic News

Medtronic Begins Enrolling U.S. IDE Study of EnliteTM Sensor for Continuous Glucose Monitoring

Study Will Evaluate Accuracy of Latest Innovation to Help People with Diabetes Improve Glucose Control

MINNEAPOLIS, Nov 09, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced a new United States investigational device exemption study to evaluate the accuracy of six-day use in adults with diabetes of its Enlite(TM) Sensor, the company's latest innovation in continuous glucose monitoring (CGM) technology for people with diabetes. The study will evaluate Enlite, a glucose sensor for CGM designed to offer improved hypoglycemic detection and comfort compared to current CGM sensors. CGM provides a more complete picture of glucose control because it can reveal high and low glucose levels that periodic fingerstick testing might miss.

The first two patients in the study were enrolled at Rainier Clinical Research Center in Seattle, Wash., and at AMCR Institute in San Diego, Calif., by the sites' principal investigators (PI), Ronald Brazg, M.D., and Timothy Bailey, M.D., respectively.

"We're very excited to move forward on a path to bring to the U.S. market this latest innovation that has been designed to provide even better accuracy, comfort and ease of use," said Francine Kaufman, M.D., Chief Medical Officer and Vice President of Global Clinical Affairs for the Diabetes business of Medtronic. "The Enlite sensor is designed to provide improved hypoglycemia detection and better overall system accuracy. The study will demonstrate whether these improvements, combined with our system's ability to predict when hypoglycemic events will occur through predictive alerts, can help people with diabetes achieve better glucose control."

The landmark clinical study STAR 3 showed that patients using Medtronic's insulin pump therapy integrated with CGM achieved a reduction in mean A1C that was four times greater than patients using multiple daily injections.1

About the Enlite Study

The Enlite study is a multi-center, randomized, prospective study designed to evaluate the performance of the Enlite Sensor in patients with diabetes during a calibration and wear period totaling 146 hours (six days). The primary study endpoint will be sensor accuracy with the minimum calibration requirements (every 12 hours after the second calibration).

The Enlite Sensor received CE *(Conformité Européenne)* Mark approval in April, 2011. Medtronic is the sole sponsor of the trial.

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.

1 Bergenstal RM, Tamborlane WV, Ahmann A, et al. [published online ahead of print June 29, 2010]*Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes*. N ENGL J MED. doi:10.1056/NEJMoa1002853.

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