Medtronic News

Medtronic Launches More Accurate and Comfortable Sensor to Help Improve Glucose Contro

Enlite(TM) SensorAvailable to Diabetes Patients for Continuous Glucose Monitoring in More Than 35 Countries

MINNEAPOLIS, Apr 11, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announces the launch of Enlite(TM) Sensor, the newest and most advanced glucose sensor for continuous glucose monitoring (CGM), in more than 35 countries outside of the United States. CGM has been shown in multiple landmark clinical studies to help diabetes patients achieve better glucose control without increasing hypoglycemia (low blood sugar), a dangerous and potentially life-threatening complication of diabetes. The Enlite Sensor combines greater comfort with improved glucose sensor performance in both overall accuracy1 and hypo detection2.

When the Enlite Sensor is used with the predictive alerts feature on Medtronic systems, diabetes patients have access to hypo detection rates up to 98%.3 This helps give early warning to people with diabetes so they can take action to prevent dangerous hypoglycemia, which is one of the major concerns of people living with diabetes.

"The Enlite Sensor will improve patients' ability to predict and detect hypoglycemia, which can be one of the most frightening aspects of living with Type 1 diabetes," Emanuele Bosi, professor of Endocrinology, Head of the Department of Internal Medicine, San Raffaele Scientific Institute and San Raffaele Vita Salute University. "CGM is an important element in managing diabetes. The STAR 3 trial demonstrated that diabetes patients achieved better glucose control when sensors were integrated with insulin pump therapy compared to multiple daily injections. Moreover, other recent studies continue to suggest that the more often patients use CGM, the greater average glucose control they can achieve without increasing hypoglycemia."

Significant design improvements make Enlite Sensor more comfortable and easier to use than the previous sensor. In a clinical study of Enlite Sensor, 85% of patients agreed that sensor insertion was pain free and 86% agreed that the Enlite insertion device was easy to use4. The Enlite Sensor is a significantly smaller sensor compared to Medtronic's previous product --69% smaller in sensor size by volume, 38% shorter in length.5 Adding to patient convenience, the Enlite Sensor can be worn on the abdomen and buttocks and used for up to six days.

"The adoption of CGM is growing rapidly, as both diabetes patients and their diabetes care professionals experience the benefits of seeing fluctuations in glucose patterns so that action can be taken to achieve better diabetes control. By making the new Enlite Sensor smaller, as well as easier to insert and wear, we expect that more people with diabetes will be able to utilize this technology to manage their condition and ultimately improve their lives," said Katie Szyman, president of the Diabetes business and senior vice president at Medtronic.

The Enlite Sensor received CE *(Conformité Européenne)* Mark approval in Paris, France and is being launched subject to other local approvals in more than 35 countries. Medtronic is working closely with the U.S. Food and Drug Administration on plans to commercialize the product in the United States. The Enlite Sensor is labeled for use with: MiniMed Paradigm(R) REAL-Time System, MiniMed Paradigm Veo(TM) System, Guardian(R) REAL-Time Continuous Glucose Monitoring System, and the iProTM2.

About Continuous Glucose Monitoring (CGM)
Diabetes patients use Personal CGM for the continuous measurement of glucose levels in the interstitial fluid (fluid found between the cells) of subcutaneous tissue. The patient inserts a disposable, needle-like sensor under the skin and the sensor transmits glucose data every five minutes to a monitor. Professional CGM is a clinician-owned device that records glucose data without patient interaction for retrospective review. CGM provides a more complete picture because it reveals high and low

glucose levels that periodic fingerstick testing might miss. The landmark clinical study STAR 3 showed that patients using insulin pump therapy integrated with CGM achieved a reduction in mean A1C that was four times greater than patients using multiple daily injections.6

In 2010, the American Association of Clinical Endocrinologists (AACE) released a consensus statement on continuous glucose monitoring which stated "CGM technology is not only novel, but it can improve the lives of patients who incorporate it into a comprehensive diabetes management plan."7 The statement recommends CGM particularly for children, adolescents and adults with frequent hypoglycemia or hypoglycemia unawareness, A1C levels over their target, large variability in glycemic levels, and the need to lower A1C levels without increasing hypoglycemic events, as well as for those who are pregnant or are planning to become pregnant.

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 While accuracy improved with all Medtronic systems, exact data varies depending upon the system the sensor is used with. In a home-use study of adult patients, Enlite Sensor's MARD was found to be 15.3% vs. 18.4% with SofSensor. MARD is the Mean Absolute Relative Difference which is a measure of average variation of sensor readings compared to Yellow Springs Instruments blood glucose analyzer reference machine readings. The lower the MARD value, the more accurate the sensor.
2 Hypoglycemia detection is the percent of time that Medtronic's CGM device correctly alerts a patient to a glucose level that is less than 3.89 mmol/L within ±30 minutes of the low glucose event occurring (when predictive alert is set to 30 minutes).
3 This refers to a +/- 30 minute event analysis. Low limit set at 3.89 mmol/L and low predictive alert set at 30 minutes. Source: Enlite Sensor Performance Addendum (for 522/722, 524/724 and Guardian)
4 Data on file
5 Data on file
6 (0.8% for SAP vs. 0.2% for MDI) ($p<0.001$).
7 American Association of Clinical Endocrinologists CGM Task Force. Consensus Statement: Continuous Glucose Monitoring. Endocrine Practice. Sept/Oct 2010; Vol 16, No 5, pp 730 - 744.

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