Medtronic News

Medtronic Receives FDA Approval for Industry's Most Advanced Integrated System for Diabetes Management

Next Generation Integrated System - MiniMed Paradigm(R) REAL-Time Revel(TM) System - Incorporates Predictive Alerts to Help Patients More Tightly Control Diabetes

MINNEAPOLIS, Mar 17, 2010 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE:MDT) today announced it has received U.S. Food and Drug Administration (FDA) approval for the MiniMed Paradigm(R) REAL-Time Revel(TM) System, the next generation of the industry's only integrated diabetes management system (insulin pump therapy, continuous glucose monitoring (CGM) and diabetes therapy management software). The system incorporates new innovative CGM features including predictive alerts that can give early warning to people with diabetes so they can take action to prevent dangerous high or low glucose events.

"Medtronic is extending its lead in the path towards the artificial pancreas with this next generation integrated system and our ongoing advancements in algorithm development," said Katie Szyman, president of the Diabetes business and senior vice president at Medtronic. "We are excited to make these leading innovations available to improve patients' lives with the industry's only integrated system in the world today. The MiniMed Paradigm Revel System can help a patient feel more secure by giving early warning of one of their greatest concerns, hypoglycemia, while continuing to simplify the complexity of diabetes management with easy-to-use features."

When using Medtronic's glucose sensors with Paradigm Revel Insulin Pumps, trend alerts can notify patients of rapid changes in glucose levels so that they can take immediate corrective or preventative action after confirming glucose levels with a fingerstick glucose measurement. Several new CGM features, including predictive and rate of change alerts, provide earlier warnings of potential glycemic excursions to help patients stay in their target range. According to recent internal study, the use of predictive alerts improved hypoglycemic event detection by 36% compared to the standard low glucose alert.1 All alerts can be customized to suit a patient's lifestyle, such as creating different settings to accommodate for exercise or to manage nocturnal hypoglycemia.

New features in the insulin pump enable patients to tailor insulin delivery to meet their personal needs. Patients who are sensitive to insulin, such as children with diabetes, now have the opportunity to deliver insulin in smaller increments (0.025 units per hour.) In addition, insulin-using type 2 patients, who are often more insulin resistant, can more tightly control their glucose levels using the new 1:1 carbohydrate ratio. The system also enables patients to set up missed meal bolus reminders.

"Recent clinical evidence clearly supports that insulin pump therapy combined with continuous glucose monitoring improves patients' A1C while reducing the relative risk of severe hypoglycemia," said William Tamborlane, M.D., professor of pediatrics and chief of pediatric endocrinology at Yale University School of Medicine. "Advances such as predictive alerts and smaller basal delivery rates can help physicians and patients customize therapy to meet individual needs. This ultimately simplifies some of the complexity of daily diabetes management."

There is a growing body of clinical evidence that continues to prove that the more often patients use Personal CGM, the greater average glucose control (A1C) they can achieve without increasing hypoglycemia, including the JDRF-Funded Studies and REAL TREND Study.23 Today, insulin pumps are covered by nearly all commercial and government insurance programs in the United States, and nearly 90 percent of type 1 diabetes patients with commercial insurance coverage have access to CGM when medical criteria is met. Personal CGM is approved for use by people ages 7 and older in the United States.

The MiniMed Paradigm REAL-Time Revel System is immediately available. Information on how to purchase the system is available at www.medtronicdiabetes.com or by calling 1-800-646-4633.

About The MiniMed Paradigm REAL-Time Revel System

The MiniMed Paradigm REAL-Time Revel System is comprised of three key components: a "smart" insulin pump, CGM and CareLink(TM) Therapy Management Software. CareLink software is a free online tool that helps diabetes patients and their healthcare providers analyze therapy and make adjustments through easy-to-read reports, charts and graphs.

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 Keenan DB, Dartaya R, Mastrototaro JJ. Accuracy of a new real-time continuous glucose monitoring algorithm.*J Diabetes Sci Technol* 2010;4:111-118.

2 The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med.* 2008;359:1464-1476.

3 Raccah D, Sulmont V, Reznik Y, et al. Incremental value of continuous glucose monitoring when starting pump therapy in patients with poorly controlled type 1 diabetes: the RealTrend study. *Diabetes Care* published ahead of print, online September 18, 2009.

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