Medtronic News

Medtronic Files PMA Application for FDA Approval of MiniMed 530G System Featuring Threshold Suspend Automation

FDA to Review World's First Insulin Pump with Threshold Suspend - Another Significant Step Toward the Artificial Pancreas

MINNEAPOLIS - June 8, 2012 -In the next step toward the development of an artificial pancreas, Medtronic, Inc. (NYSE:MDT) today announced that it has filed the final module of its Pre-Market Approval (PMA) application with the U.S. Food and Drug Administration for the MiniMed® 530G system featuring Threshold Suspend Automation. If approved by the FDA, the MiniMed® 530G system will be the only integrated insulin pump and continuous glucose monitor in the United States that automatically suspends insulin delivery if the sensor glucose value is equal to or below the low threshold value.

Medtronic's PMA submission includes data from the in-clinic ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) study, which met its efficacy endpoints and showed a reduction in time spent below the low glucose threshold in people with diabetes using the Threshold Suspend Automation feature, compared to conventional pump therapy. The in-home ASPIRE study is still ongoing.

"There is a clear need for new therapies that can stop insulin delivery when glucose becomes dangerously low, which could be of great benefit if a person with diabetes is asleep or unable to react," said Richard M. Bergenstal, M.D., executive director of the International Diabetes Center at Park Nicollet Health Services in Minneapolis and Clinical Professor for the Department of Medicine at the University of Minnesota. "Reducing the amount of time spent below the low glucose threshold without rebound hyperglycemia (high blood sugar) could help people with diabetes stay in better, overall glucose control."

"We are excited about the potential to bring low glucose suspend innovation to market in the United States to meet the unmet clinical needs in the treatment of diabetes ," said Katie Szyman, president of the Diabetes business of Medtronic. "This PMA application is a demonstration of our commitment to advance the science and development of insulin delivery and continuous glucose monitoring systems to commercialize an artificial pancreas."

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. Each year nearly one in 14 people with insulin-treated diabetes will experience one or more episodes of severe hypoglycemia.1

In addition, this PMA submission includes data from the pivotal trial of the Enlite® sensor, Medtronic's newest and most advanced continuous glucose sensor. The Enlite sensor is smaller for greater comfort and has been designed to offer improved accuracy and greater hypo detection capabilities, compared to Medtronic's Sof-Sensor®.

About Threshold Suspend Automation

The MiniMed 530G system is the first-of-its kind system that features an insulin pump integrated with continuous glucose monitoring, as well as advanced software algorithms that enable Threshold Suspend Automation. Threshold Suspend works by automatically stopping insulin delivery temporarily if sensor glucose level is equal to or below the low threshold value.

Until Threshold Suspend Automation, there has never been an approved therapy in the United States to automatically intervene when sensor glucose becomes severely low. Medtronic hopes to be the industry leader in bringing this important new feature to people with diabetes in the United States.

Medtronic leads the industry in investments in research, development and clinical science as part of its continued commitment to develop an artificial pancreas, a system that closely mimics the insulin delivery of a healthy pancreas using advanced

technology that continuously monitors glucose levels and automatically adjusts insulin delivery with minimal or no patient interaction.

About Diabetes

According to the Centers for Disease Control and Prevention, diabetes affects nearly 24 million Americans; of that, nearly one-quarter, or six million people, do not know they have the disease. Diabetes is the sixth leading cause of death in the United States and costs approximately $174 billion per year in direct and indirect medical expenses.

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; 2003:1176-1180.

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