Medtronic News

Medtronic Gains Approval of First Artificial Pancreas Device System with Threshold Suspend Automation

(Thomson Reuters ONE via COMTEX) --MiniMed® 530G with Enlite® Automatically Stops Insulin Delivery If Sensor Glucose Levels Fall Below a Predetermined Threshold

MINNEAPOLIS - September 27, 2013 -Medtronic, Inc. (NYSE:MDT) today announced the U.S. Food and Drug Administration (FDA) approval of the MiniMed® 530G with Enlite®, a breakthrough, first-generation artificial pancreas system with Threshold Suspend automation for people with diabetes. Medtronic's system is the first in the United States that can automatically stop insulin delivery when sensor glucose values reach a preset level and when the patient doesn't respond to the Threshold Suspend alarm. The MiniMed 530G system incorporates the new Enlite sensor, Medtronic's most accurate and comfortable continuous glucose sensor with a 31 percent improvement in overall accuracy from the previous generation.[i]

"The diabetes community has eagerly awaited approval of this system that stops insulin delivery when sensor glucose values fall below a predetermined threshold," 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. "We are hopeful that advances such as this and improvements in the accuracy of continuous glucose sensors will help people with diabetes strive for better control of their diabetes."

"We're excited to bring yet another important 'first' to the United States. The MiniMed 530G with Enlite can help people gain better control of their diabetes versus multiple daily injections," said Katie Szyman, president of the Diabetes business at Medtronic. "We are committed to advancing closed loop algorithms, continuous glucose monitoring and insulin delivery technologies to bring new artificial pancreas systems to market."

The Enlite sensor delivers better comfort and reliable CGM accuracy. In addition to the 31 percent improvement in overall accuracy, the Enlite sensor detects up to 93 percent of hypoglycemia episodes when predictive and threshold alerts are on.[ii] The Enlite sensor is also 69 percent smaller[iii] than the previous Medtronic sensor, to deliver improved comfort in using continuous glucose monitoring. The new Enlite serter provides a simpler sensor insertion process with a hidden-introducer needle.

The MiniMed 530G system was approved for use by people with diabetes ages 16 and older. Medtronic will conduct a post-approval study including children ages two and older. The Enlite sensor can be worn for six days.

As a condition of approval, in addition to the post-approval study, Medtronic will engage in direct patient follow up and will make certain manufacturing accommodations. These commitments are consistent with the product approval by the FDA and an accompanying warning letter issued to Medtronic on Sept. 19, 2013. Medtronic has already addressed many of the observations noted in the warning letter and is committed to resolving the remaining observations as quickly as possible and in accordance with the product approval requirements. Medtronic is committed to providing safe and effective products for people with diabetes.

Medtronic will begin ramping up production immediately to prepare for a launch of the MiniMed 530G in the next several weeks. In the meantime, customers can find additional product and important safety information at www.medtronicdiabetes.com.

Artificial Pancreas System with Threshold Suspend Automation

The MiniMed 530G system is the first system approved under the new product classification, "OZO: Artificial Pancreas Device System, Threshold Suspend," created by the U.S. Food and Drug Administration. Threshold Suspend automation automatically

stops the delivery of insulin if glucose levels reach a threshold, which can be set by a healthcare provider between 60-90 mg/dL. Once the threshold is met, the MiniMed 530G system will first alert the wearer with an alarm. If the individual is sleeping, unconscious or otherwise unable to react, the system will suspend all insulin delivery for two hours. Insulin delivery can be resumed at any time.

When Medtronic develops a next generation product for diabetes control, it will be designed to fully replicate the function of the pancreas by automatically monitoring glucose levels and delivering appropriate insulin to people with Type 1 diabetes; this future "fully automated artificial pancreas" will truly require minimal to no interaction by the patient user.

Multimedia Release

A multimedia version of this release, with downloadable graphics, can be found at: http://bit.ly/1fLeDiG

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.

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[i]MiniMed Paradigm REAL-Time Revel with Sof-sensor User Guide and Enlite®.

[ii]MiniMed 530G user guide. This refers to a +/- 30 minute event analysis. Low limit set at 70 mg/dL and low predictive alert set at 30 minutes. The false alert rate was 33% using the same analysis.

[iii]According to the MiniMed Paradigm REAL-Time Revel User Guide and MiniMed 530G User Guide

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