Medtronic News

Medtronic Begins Overnight Artifical Pancreas Study

(Thomson Reuters ONE via COMTEX) --Study Marks Critical Milestone Toward Commercialization of a Third-Generation

Artificial Pancreas System for People with Diabetes

MINNEAPOLIS - June 24, 2013 - Medtronic, Inc. (NYSE:MDT) today announced the first patient enrollments in the U.S. Overnight Closed Loop Study, a key feasibility trial to begin the commercialization path for a third-generation, fully automated artificial pancreas system for people with diabetes. Under an investigational device exemption granted by the U.S. Food and Drug Administration, the study will examine a closed loop algorithm that is designed to automatically achieve a specified target glucose value throughout the night. The in-clinic study will also test Medtronic's breakthrough fault detection technology, which will be critical to the commercialization of a safe and effective system.

"For people with diabetes, controlling blood sugars through the night can be frustrating. Too much insulin can cause the blood sugar to go too low. Not enough insulin will result in waking up with blood sugar too high, making the next day's diabetes management challenging," said Timothy Bailey, M.D., director of AMCR Institute. "Technology that safely and automatically adjusts insulin delivery overnight would allow people with diabetes to wake up with normal blood sugars. This in turn could improve overall diabetes control with less anxiety, significantly improving the daily lives of people with diabetes. This is why the findings from this trial will be so important."

This system - classified by the FDA as a Control-To-Target system - is a fully automated system that requires no interaction from the user (except for calibration of the continuous glucose monitoring system). Going a step beyond systems that only manage blood glucose to a broad target range, this system automatically adjusts insulin delivery to achieve a specific glucose value, such as 120 mg/dL.

Up to 85 subjects will be enrolled at six investigational centers in the United States. Overnight in the clinic, trial participants will use Medtronic's closed loop, artificial pancreas system consisting of a MiniMed® insulin pump, continuous glucose monitor and an Android phone. The in-clinic study will test the system's breakthrough fault detection technology by simulating system failures and examining the algorithm's ability to prevent the over- or under-delivery of insulin in even the most unlikely circumstances.

"For more than a decade, Medtronic has been conducting clinical research of artificial pancreas systems, working toward bringing to market systems that think, act and communicate through cutting-edge automation and connectivity to help patients spend less time worrying about and managing their diabetes and more time living," said Francine Kaufman, chief medical officer and vice president of global clinical affairs for Medtronic Diabetes. "The safety and reliability of these artificial pancreas technologies is absolutely critical. This study is the first to put closed loop algorithms to the test, simulating the 'worst case' scenarios to ensure patient safety should a fault occur."

Additional trial details, including enrollment information, can be found at ClinicalTrials.gov.

The U.S. Overnight Closed Loop Study is the latest in Medtronic's 10-year history of clinical trials that examine different elements of the closed loop algorithms to evaluate both safety and efficacy. Additional overnight closed loop studies using Medtronic's algorithm are currently underway in Australia and the United Kingdom. An evaluation of overnight closed loop in a diabetes camp setting will be beginning in California.

To date, Medtronic's breakthroughs in diabetes technology include:

- The first integrated insulin pump and continuous glucose monitoring system, the foundation upon which artificial pancreas technologies are built. (2006)

- The first system to automatically suspend insulin delivery based on pre-set threshold sensor glucose values, which is commercially available in over 50 countries around the world and currently undergoing review with the FDA. (2009)

- A second-generation artificial pancreas system that automatically suspends insulin delivery when glucose values are predicted to reach a low threshold and then resumes insulin delivery once those glucose levels recover, a product nearing commercialization in Europe.

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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