



Medtronic

NEWS RELEASE

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FOR IMMEDIATE RELEASE

**MEDTRONIC ACCELERATES PATH TO ARTIFICIAL PANCREAS WITH NEW
MINIMED 640G DATA AND START OF HYBRID CLOSED LOOP TRIAL**

*MiniMed 640G System Shown to Further Reduce Hypoglycemia; Pivotal Study to Examine
Safety of Hybrid Closed Loop System for People with Diabetes*

BOSTON – June 6, 2015 – As part of its commitment to developing an artificial pancreas for people with diabetes, Medtronic plc (NYSE:MDT) today announced results from the European User Evaluation of the MiniMed® 640G system, which demonstrated that the pump’s exclusive SmartGuard technology can reduce hypoglycemia (low blood glucose) and offer further advancement in automation compared to previous generation Medtronic insulin pump systems. The results will be presented in a poster session at the American Diabetes Association 75th Scientific Sessions on Sunday, June 7 at 12:00pm in Hall B at the Boston Convention and Exhibition Center. Medtronic also announced that patient enrollment has begun in the first ever pivotal study of a Hybrid Closed Loop system, which is designed to automatically control glucose levels 24 hours a day with less input from patients.

MiniMed 640G User Evaluation Study

Prior to the international launch of MiniMed 640G earlier this year, a user evaluation was conducted at three European sites with 40 pediatric and adult participants with

type 1 diabetes using the MiniMed 640G system for 30 days. The system's SmartGuard technology, specifically its Suspend before Low feature, is designed to automatically suspend insulin delivery when sensor glucose levels are predicted to approach a low limit, and automatically resume insulin delivery once sensor glucose levels recover. Final data showed that there were 2402 Suspend events (2322 Suspend before Low events, 80 Suspend on Low events). In 83.1 percent of the Suspend before Low events where the pump stopped delivering insulin, the patients' sensor glucose never reached the pre-set low limit.

"Severe hypoglycemia can have devastating effects on people with diabetes and even milder episodes can really impair quality of life," said Pratik Choudhary, M.D., senior lecturer and consultant in diabetes at King's College London and one of the lead investigators in the European User Evaluation. "The more we can do to minimize the impact of hypoglycemia, the better we can make lives of people with diabetes. That is why patients in our user evaluation really loved MiniMed 640G with SmartGuard technology, because it effectively and unobtrusively reduced hypoglycemia."

The MiniMed 640G system includes a new insulin pump design to provide convenient diabetes management with a simple user interface, full-color screen, waterproofing¹ and remote bolus. The product is approved for investigational use only in the U.S., where a large, multi-center pivotal trial is currently underway.

Hybrid Closed Loop Pivotal Study

Medtronic also announced the first patient was enrolled in the pivotal study to determine the safety of its Hybrid Closed Loop system, a key step to bringing the technology to the U.S. and international markets. Building on the breakthrough technology in the MiniMed 640G system, the Hybrid Closed Loop system is designed to

automatically control glucose levels 24 hours a day with less input from patients. People using the system will only need to enter their carbohydrates at mealtime, and calibrate the sensor periodically, significantly simplifying today's diabetes management routines.

"Insulin pumps and continuous glucose monitoring systems have greatly improved the ability for people with diabetes to achieve better glucose control and live longer, healthier lives," said Satish Garg, M.D., professor of pediatrics and medicine and director of the adult diabetes program at the University of Colorado Barbara Davis Center for Childhood Diabetes. "However, even with these systems, patients must make hundreds of decisions each day. Simplifying this self-management with a more automated Hybrid Closed Loop system would have a very meaningful impact on these patients' lives."

This is the first pivotal trial of closed loop technology conducted in the U.S. As Medtronic's largest and longest at-home closed loop study, this single-arm, multi-center, home and hotel clinical study will enroll up to 150 patients aged 14-75 with type 1 diabetes on insulin pump therapy. Medtronic's new insulin pump platform and fourth-generation sensor will be used in this trial. Additional trial details, including enrollment information, can be found at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01857973) (Identifier: NCT01857973)

"After years of research and development, the critical components of a closed loop system are here," said Francine Kaufman, M.D., chief medical officer and vice president, global medical, clinical & health affairs at Medtronic Diabetes. "We are thrilled to be partnering with the world's leading investigators to do the clinical work to bring this technology to market so that it can help people with diabetes enjoy even greater freedom and better health."

Additional Posters Presented at ADA on Medtronic Advancements Toward an Artificial Pancreas:

- **Impact of Overnight Home Closed Loop (CL) Insulin Delivery on Glycemia and Counter-Regulatory Hormones Compared to Sensor Augmented Pump Therapy with Low Glucose Suspend (SAP-LGS):** Randomized, controlled cross-over study to evaluate the performance of a uni-hormonal artificial pancreas (proportional integral derivative with insulin feedback algorithm). Speaker: A. Sharifi, Sunday, June 7 at 12:00pm in Hall B.
- **Utilization of Pump Alert Settings by Intervention versus Control Subjects in the ASPIRE In-Home Study Evaluating Automatic Threshold Suspend:** Further analysis of the ASPIRE in-home study to test whether a reduction in nocturnal hypoglycemia was attributable to between-group differences in alert settings related to sensor glucose values. Speaker: J. Shin, Sunday, June 7 at 12:00pm in Hall B.
- **Glycemic Control Post Suspension of Insulin Using the Threshold Suspend Feature:** Additional analysis of the ASPIRE study to assess whether the reduction in hypoglycemia seen with the Threshold Suspend feature was associated with a significant increase in hyperglycemia. Speaker: J. Shin, Saturday June 6 at 11:30am in Hall B and Sunday, June 7 at 12:00pm in Hall B.
- **Medtronic's Hybrid Closed-Loop System - An Evaluation of Meal Dosing:** Studied whether standardized and relatively aggressive carbohydrate ratios could significantly improve the system's performance by reducing postprandial hyperglycemia without increasing the risk of hypoglycemia. Speaker: B. Grossman, Sunday, June 7 at 12:00pm in Hall B.

Multimedia Release

A multimedia version of this release, with downloadable graphics can be found at:

<http://bit.ly/1Qx9ES8>

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)

Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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¹ MiniMed 640G is waterproof in up to 12 feet of water for up to 24 hours. See IFU for care instructions to help maintain waterproof.