Medtronic Presents U.S. Pivotal Trial Data for MiniMed™ 780G Advanced Hybrid Closed Loop System with Automated Correction Bolus Feature

Data from Two Key Clinical Trials of the Next-Generation Medtronic Automated Insulin Pump Demonstrates Positive Results for Patients with Type 1 Diabetes

DUBLIN, June 12, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today presented results from its U.S. pivotal trial of its investigational MiniMed™ 780G Advanced Hybrid Closed Loop (AHCL) system at the virtual 80th Scientific Sessions of the American Diabetes Association (ADA). The MiniMed 780G system, which features a default target of 100mg/dL (with the option of 120mg/dL), programmable insulin action time from two to eight hours, and automatic corrections every five minutes, met all study endpoints and demonstrated high user satisfaction across the studies being presented today at the conference.

Results of the 90-day at home U.S. pivotal trial, studying adults and adolescents aged 14-75 years old, show the trial successfully met both safety and glycemic endpoints and demonstrated no occurrences of severe adverse events. The trial results include:

- No severe hypoglycemia and diabetic ketoacidosis
- Average A1C of 7.0%
- Overall Time in Range (defined as 70-180 mg/dL) of 75%, with overall Time Below Range (defined as less than 70 mg/dL) of 1.8%
- Overnight Time in Range of 82%, with overnight Time Below Range of 1.5%
- Autocorrection contributing to 22% of all bolus insulin
- Participants being in SmartGuard™ (closed loop) 95% of the time
- Mean sensor glucose (SG) of 148 mg/dL overall, and 144 mg/dL at the default 100mg/dl target

Results from a study questionnaire also demonstrated high user satisfaction with 96% indicating it was easy to use. System requests for fingerstick blood sugars were also reduced by 46% when compared to the MiniMed™ 670G system.

Lastly, the lower target glucose and active insulin time (AIT) settings substantially improved Time in Range, without increasing hypoglycemia. Time in Range increased to 76%, with a 100 mg/dL target and AIT of two to three hours and reached 79% when AIT was set to two hours. Results across all pump settings exceeded ADA and ATTD international clinical consensus Time in Range guidelines.

	Setting	Overall: Time in Range	Daytime: Time in Range	Overnight: Time in Range
100 mg/dL default target	2-3 hour active insulin time (AIT)	76%	74%	84%
	2 hour AIT	79%	76%	87%

"The results of the study are exciting and are a welcome addition to what we have seen with other advancements in automated insulin delivery systems. Most notable is the additional target glucose level of 100 mg/dL – which will be lower than the other commercially available devices in this category and likely contributed to the demonstrated improvements in study outcomes, namely Time in Range and A1C," said Dr. Anders Carlson, medical director of the Park Nicollet International Diabetes Center (IDC) in Minneapolis, Minn. and investigator of the study. "We often hear from our patients about wanting lower glucose target settings, and there is certainly a desire to see that represented more in the current marketplace. I'm pleased to see this next generation closed loop system continuing to improve in that direction."

Data from a second, randomized cross-over clinical trial based in New Zealand studied a more challenging patient group, including those with less-controlled diabetes and a younger patient population of children as young as seven years old, was also presented at the meeting. The results demonstrated improved outcomes for those on the Medtronic AHCL system when compared to a predictive low-glucose management (PLGM) algorithm, even for this patient group which entered the trial at a low baseline. The results included:

- A 13 point overall improvement in Time in Range to 70.4%
- A 0.4% overall decrease in Time Below Range (70mg/dL) to 2.1%

- A 16% improvement in Time in Range overnight, due in large part to a 12% reduction in hyperglycemia
- A 13.0% improvement in Time in Range to 70.2% at the default 100mg/dl target
- Autocorrection contributing to 21% of all bolus insulin
- Participants being in SmartGuard (closed loop) 95% of the time
- Mean SG improvement of 10 mg/dL overall

The study met primary endpoints (increasing overall Time in Range), as well as secondary endpoints (decreasing overall time above and below range). Patients also reported through a study questionnaire being highly satisfied with their experience overall, with 95% agreeing that the system was easy to use and 85% agreeing that the system improved their quality of life.

"We wanted to design a system that further simplifies diabetes management and provides an extra layer of protection for the times one may forget a pre-meal bolus or miscalculate their carbohydrates," said Robert Vigersky, M.D., chief medical officer for the Diabetes Group at Medtronic. "The combination of these two study findings, across a broad spectrum of patients at various levels of glucose control, are promising – they demonstrate that the smart automation featured in this next-generation system has tremendous potential for meaningfully reducing burden and enhancing quality of life."

The investigational MiniMed 780G system is designed to automate the delivery of both basal insulin and correction boluses every five minutes to help people with diabetes avoid highs and lows with greater ease. Bluetooth® connectivity will also enable real-time monitoring of glucose levels and trends on smartphones by both the user and their care partners. Data from the pivotal study will be submitted as part of a future Premarket Approval (PMA) application to the U. S. Food and Drug Administration (FDA) for commercial approval of the MiniMed 780G system in the U.S. In the United States, the MiniMed 780G system is investigational use only, and not approved for sale or distribution. The MiniMed 780G system received CE (Conformité Européenne) Marking in June 2020.

The findings outlined above will be shared at the 80th Scientific Sessions of the American Diabetes Association virtual meeting, June 12-16, 2020:

- "Safety and Glycemic Outcomes of the MiniMed Advanced Hybrid Closed-Loop (AHCL) System in Subjects with T1D" symposium presentation by Dr. Bruce Bode on Friday, June 12 at 2:00 p.m. CDT and late breaking poster presentation by Dr. Anders Carlson on Saturday, June 13 at 10 a.m. CDT.
- "Improved Glycemic Outcomes with Medtronic MiniMed™ Advanced Hybrid Closed-Loop Delivery: Results From a Randomized Crossover Trial Comparing Automated Insulin Delivery With Predictive Low Glucose Suspend in People with Type 1 Diabetes" – symposium presentation on Friday, June 12 at 2:00 p.m. CDT and oral presentation on Sunday, June 14 at 3:15 p.m. CDT, both presented by Dr. Martin de Bock.

Other data on the AHCL system at the 80th Scientific Sessions of the American Diabetes Association virtual meeting include:

- "Improved Technology Satisfaction and Sleep Quality with Medtronic MiniMed Advanced Hybrid Closed Loop Delivery Compared with Predictive Low Glucose Suspend in People with Type 1 Diabetes in a Randomized Crossover Trial" – poster presentation by Dr. Olivia Collyns and Dr. Martin de Bock on Saturday, June 13 at 10:00 a.m. CDT.
- "Postprandial glucose control using the Medtronic Advanced Hybrid Closed-Loop System: Faster Acting Insulin Aspart vs. Insulin Aspart" oral presentation by Dr. Melissa Lee and Dr. David O'Neal on Sunday, June 14 at 5:15 p.m. CDT.
- "Unannounced Meals at Home with The Medtronic Advanced Hybrid Closed Loop"– poster presentation by Dr. Amir Tirosh on Saturday, June 13 at 10:00 a.m. CDT.

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 among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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