



## Medtronic Initiates Pivotal Trial for Bluetooth Enabled MiniMed(TM) 780G Advanced Hybrid Closed Loop System Designed to Automate Correction Bolusing

June 8, 2019



**DUBLIN - June 8, 2019** - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the enrollment of the first study participants in the company's pivotal trial of its Bluetooth® enabled MiniMed(TM) 780G advanced hybrid closed loop (AHCL) system. This next-generation system is designed to automate the delivery of correction boluses when the user experiences, or is predicted to experience, prolonged high glucose levels based on their sensor readings. The trial will evaluate the safety of the MiniMed 780G system in participants with type 1 diabetes at home, at work, during exercise and other daily activities. The study will enroll up to 350 adult and pediatric participants.

"We are excited to begin enrollment in this trial as we continue to advance our phased approach towards the development of a fully closed loop system. The MiniMed 780G system is designed to take our MiniMed 670G system with automated basal insulin delivery one step further so that people living with type 1 diabetes can enjoy greater freedom and less burden from their daily diabetes management," said Robert Vigersky, M.D., chief medical officer for the Diabetes Group at Medtronic. "Forgetting a pre-meal bolus can lead to hyperglycemia and we recognize that as much as people try to remember to take a pre-meal bolus or to accurately calculate their carbohydrates, real life sometimes gets in the way. As we evaluate this next-generation system, our goal is to increase automation through smart algorithms that reduce the need for patient interaction and decision-making."

Data from the feasibility study demonstrated the safety of the system and its potential to improve overall glycemic control and simplify diabetes management for individuals who forget to administer a bolus of insulin at mealtime, carb count inaccurately or choose to forgo announcing meals. Additionally, hypoglycemia (time spent below 70mg/dL) dropped by 27% and hyperglycemia (time spent above 180 mg/dL) was reduced by 14% with no serious adverse events reported.

"The early results are positive and I look forward to evaluating the system in more patients as part of the pivotal trial as the technology holds significant promise for the diabetes community," said Dr. Robert Slover, director of pediatrics at the Barbara Davis Center for Diabetes and co-principal investigator of the study. "Managing diabetes on a daily basis is a tremendous burden and responsibility so I'm very pleased to see advancements being made in the space that will enable technology to safely automate more of these decisions on behalf of patients so they can think less about their disease."

When evaluating user feedback to the system, 100% of participants in an Australia-based feasibility study led by Dr. David O'Neal rated the MiniMed 780G system as the best therapy they have ever used, and reported their overall satisfaction as extremely satisfied or very satisfied. Across both feasibility studies, high satisfaction was tied to overall improvement in Time in Range, reduced high glucose levels after meals, increased time in Auto Mode, and reduced daily effort required to manage diabetes, as the number of Auto Mode exits, alerts and fingerstick requests were all significantly reduced. All participants stated that they trusted the system to take care of their glucose and that it significantly increased their flexibility and confidence in taking care of their diabetes.

These data were shared during poster and E-poster Theater presentations at the 79th Scientific Sessions of the American Diabetes Association, in San Francisco, June 7-11, 2019:

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- "Evaluation of a Medtronic Enhanced Hybrid Closed-Loop (e-HCL) System During Unannounced Meals of Medium Size" - E-poster Theater presentation by Dr. Anirban Roy on Saturday, June 8 at 11:30 a.m. PDT, and poster presentation on Sunday, June 9 at noon.
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- "Feasibility study of a hybrid closed-loop system with automated correction boluses" - E-poster Theater presentation by Dr. Revital Nimri on Saturday, June 8 at 11:30 a.m. PDT, and poster presentation on Sunday, June 9 at noon.

For more details, including enrollment information for the clinical trial, please visit <https://clinicaltrials.gov/ct2/show/NCT03959423>

### **Analyst and Investor Briefing**

Medtronic will host a webcast to highlight its Diabetes Group on Sunday, June 9, 2019 from 11:00 a.m. to 12:00 p.m. PDT. The webcast will feature remarks from Medtronic management, including comments on Medtronic's clinical data and product pipeline. The live audio webcast can be accessed by clicking on the Investor Events link at <http://investorrelations.medtronic.com> on June 9th. Within 24 hours of the webcast, a replay will be available on the same webpage. This event is not part of the official ADA Scientific Sessions.

### **About the Diabetes Group at Medtronic** ([www.medtronicdiabetes.com](http://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](http://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.

**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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