Medtronic News

New Study Demonstrates Safety and Effectiveness of the MiniMed(TM) 640G System Reducing Hypoglycemia Compared with Insulin Pump Therapy Without CGM in Type 1 Diabetes

DUBLIN – May 9, 2019 – Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the publication of the SMILE study in *The Lancet Diabetes & Endocrinology*.1The SMILE study (Study of MiniMed 640G Insulin Pump with SmartGuardTM in prevention of Low Glucose Events in adults with Type 1 diabetes) is the largest randomized controlled trial to investigate the effectiveness and safety of the MiniMed™ 640G system with SmartGuard™ Suspend before low technology compared to insulin pump therapy without continuous glucose monitoring (CGM) in decreasing hypoglycemia (low blood sugar). The study was conducted with adults with type 1 diabetes (T1D) prone to severe hypoglycemia, a condition that can cause confusion, disorientation, loss of consciousness, seizures, and in the worst cases can result in coma or death.

"This new data adds to the robust body of evidence of our insulin pump systems and demonstrates the clinical effectiveness of our SmartGuardTM technology – available both within the MiniMed 640G and the MiniMed™ 670G systems. Additionally, these results were achieved with a group of patients that are among the most challenging to treat successfully," said Dr. Robert Vigersky, chief medical officer, Global Medical and Clinical Affairs for the Diabetes Group at Medtronic. "Medtronic is committed to continuous technology innovation and expanding access to our therapies. These results further support our focus to deliver improved glycemic control while reducing the burden of people living with diabetes."

The SMILE study was conducted at 16 centers in France, Italy, United Kingdom, the Netherlands and Canada, and 153 adults, followed up for 6 months, were included in the study analysis. The MiniMed 640G system with SmartGuard Suspend before low had already been proven to reduce hypoglycemia compared to Sensor-Augmented Pump (SAP) therapy in people with T1D.2,3 Now, the SMILE study demonstrated the effectiveness of the system in reducing hypoglycemia compared to insulin pump therapy without CGM in adults at increased risk of severe hypoglycemia. In addition, the study showed improvement in the amount of Time in Range spent by people using the MiniMed 640G system with SmartGuard Suspend before low versus those using insulin pump therapy without CGM.

The SMILE study outcomes were partially presented ahead of its publication at the 12th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2019), in Berlin, in February 2019. The SMILE study results suggest that the therapy would be clinically beneficial for patients impacted by hypoglycemia exposure.

"The study demonstrated the MiniMed 640G system with SmartGuard Suspend before low was associated with significant reduction in both biochemical and severe hypoglycemia compared to insulin pump therapy. This reduction, including 84 percent fewer events of severe hypoglycemia, was achieved without increasing HbA1c levels. The clinical outcomes improvements were more pronounced during the night, when hypoglycemic episodes are most problematic," said Professor Emanuele Bosi, from the Diabetes Research Institute, Vita Salute San Raffaele University & San Raffaele Hospital, Milan, Italy. "Another important conclusion is that patients using SmartGuard Suspend before low showed less fear of hypoglycemia and higher satisfaction with their treatment. Hypoglycemia unawareness and fear of hypoglycemia has a major impact on people with diabetes and their loved ones' lives. These results confirm the confidence that I have in this advanced technology, and the improvement it provides to my patients in glycemic control and quality of life."

SmartGuardTMTechnology

SmartGuard is Medtronic's exclusive technology that mimics some of the functions of a healthy pancreas. Each advancement of SmartGuard technology takes on more tasks of diabetes management to help improve glycemic control. SmartGuardSuspend

before low feature suspends insulin delivery when sensor glucose is approaching a pre-set low limit, thus helping to prevent hypoglycemia.

The MiniMed 670G system incorporates the Suspend before low feature into its "Manual Mode" and then advances the technology by automating and personalizing the delivery of basal insulin 24 hours a day. It is the only commercially available technology in the world that proactively minimizes the occurrence of hypoglycemia through automatically adjusting basal rate.

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 86,000 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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1. Bosi E, et al. Lancet Diabetes Endocrinol. Published online, April 29, 2019. doi:https://doi.org/10.1016/S2213-8587(19)30150-0.

2. Biester T, et al. Diabetes Technol Ther. 2017;19(3):173-182.

3. Abraham BA, et al. Diabetes Care 2017;41(2):303-310.

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