Medtronic News

Medtronic Wraps Up Scientific Data Presentations at the Advanced Technologies and Treatments for Diabetes International Conference

DUBLIN - February 25, 2019 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced a successful conclusion to the 12th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2019), which took place in Berlin from February 20 - 23, 2019.

At this year's conference, the Diabetes Group at Medtronic presented a range of scientific data focusing on the company's latest MiniMed(TM) 670G system and its exclusive SmartGuard(TM) technology, including new pediatric data and the importance of Time in Range, defined as the percentage of time people with diabetes spend between the glucose range of 70-180 mg/dL (3.9-10 mmol/L). Medtronic also shared 6-month data assessing the safety and the efficacy of the MiniMed(TM) 640G system's ability to reduce hypoglycemia compared to insulin pump therapy without continuous glucose monitoring (CGM) in an adult population. Finally, data were also presented on future technologies that aim to improve an insulin pump system's ability to automatically adjust for meals, supporting the company's goal to reduce the burden of diabetes management.

"Medtronic is committed to continuous technology innovation and expanding access to our unique insulin pump systems," said Dr. Robert Vigersky, principal medical officer, Global Medical and Clinical Affairs for Diabetes Group at Medtronic. "These data, especially our ongoing focus to improve Time in Range and reduce hypoglycemia, will continue to guide our path forward to help alleviate the burden of living with diabetes."

Here is a recap of the major scientific presentations that took place:

Scientific Presentations

- "Effectiveness and safety of 6-month MiniMed 640G system use in adult patients prone to hypoglycemia"1

- This was the first presentation on the SMILE study, prior to its publication. (SMILE study - Study of MiniMed 640G Insulin Pump with SmartGuard in prevention of Low Glucose Events in adults with Type 1 diabetes) This 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 CGM in decreasing hypoglycemia in adults with type 1 diabetes (T1D) prone to hypoglycemia.
- The Suspend before low feature of the MiniMed 640G system effectively reduced hypoglycemia, including severe hypoglycemia, when used for 6 months by hypoglycemia-prone adults with type 1 diabetes, compared pump therapy without CGM. There was no increase in HbA1c and no episodes of diabetic ketoacidosis. Sensor-based hypoglycemic events were reduced from 4.13 ± 3.36 to 1.12 ± 1.23 events per week and the rate of severe hypoglycemia (needing assistance, seizure or coma) was reduced from 52.1 to 8.5 events per 100 patient-years.
- The results suggest that the therapy would be clinically beneficial for patients impacted by hypoglycemia exposure. The MiniMed 670g system has not been approved by the U.S. Food and Drug Administration (FDA).

- "The relationship of hemoglobin HbA1c to CGM-derived Time in Range in patients with diabetes"

- The relationship between Time in Range and HbA1c had not been clearly defined; A meta-analysis of 18 studies data showed that there was a good correlation between the two measurements, in that a 10 percent change in Time in Range (e.g., between 50 percent and 60 percent) is associated with a 0.8 percent change in HbA1c.
- The data supports that a combination of the two metrics may best characterize overall glycemic control at this time.

- "Time in target glucose range and glycated hemoglobin levels during the MiniMed 670G system pivotal trials"

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- Children, adolescents and adults using the MiniMed 670G system with SmartGuard technology for 3 months had improved Time in Range and a lower HbA1c compared to baseline.
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- The data supports that a combination of the two metrics may best characterize overall glycemic control.

- "Glycemic outcomes during MiniMed 670G system use by children aged 2-6 years with T1D"

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- To support the company's goal of bringing the MiniMed 670G system technology to new and expanded patient populations, data was presented on 3-month use of the system among patients 2-6 years of age.
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- Data showed that in-home use of the system in the younger population was safe and associated with improved glycemic metrics, such as a reduction in HbA1c (8.0 ± 0.9 percent to 7.5 ± 0.6 percent) and increased Time in Range (55.4 ± 13.3 percent to 63.6 ± 9.3 percent), when compared to baseline (sensor-augmented pump therapy without insulin delivery automation). The percentage of time spent above 180 mg/dL was also reduced.
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- These data mirror the results in older youth and adults with type 1 diabetes using the MiniMed 670G system. The MiniMed 670G system has not been approved by the FDA for this population.

- "A hybrid closed-loop (HCL) system that addresses unannounced meals"

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- A preliminary study of a prototype enhanced hybrid closed loop system demonstrated the ability to minimize hyperglycemia exposure due to a missed pre-meal bolus, or unannounced meal.
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- Preliminary data from the prototype system showed that hyperglycemia exposure due to an unannounced, medium-sized meal of 40 grams of carbohydrate was minimized to have the same approximate impact as a large-sized meal of 80 grams that had been reported to the system ahead of consumption.

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 SMILE Study - Effectiveness and Safety of 6-month MiniMedTM 640G System use in patients prone to Hypoglycemia. Data on file.

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