Advanced Hybrid Closed Loop System Early Feasibility Data on Patients Undergoing Unannounced Meal Challenges Shows Promising Results

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Positive Data on Many Medtronic Innovations Presented at ATTD: Extended Wear Infusion Set Designed to Last Twice as Long, MiniMed™ 670G System Real-Life Performance in Europe, and ProCGM Use in Type 2 Diabetes Patients

DUBLIN, Feb. 24, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced a successful conclusion to the 13th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2020), which took place in Madrid, Spain, from February 19 - 22, 2020.

At this year's conference, the Diabetes Group at Medtronic presented a range of scientific data focusing on the company's:

- **Advanced hybrid closed loop system** which is currently in pivotal trials and aims to improve patient experience and outcomes;
- Latest **extended wear infusion set technology**, which is designed to last at least twice as long as current infusion sets while providing comfort of wear;
- **MiniMed™ 670G system** real-world data in Europe, which showed the hybrid closed loop system is delivering improved glycemic control across all glucose ranges in clinical and real-world settings; and
- **Professional CGM (proCGM)**, with cost-effectiveness data showing the potential of the device's economic value in people with type 2 diabetes.

"Medtronic is committed to driving product innovation that prioritizes clinical outcomes and improves patient experience," said Dr. Robert Vigersky, chief medical officer, Global Medical and Clinical Affairs for Diabetes Group at Medtronic. "These data underscore our commitment to continually creating new technologies that improve time in range and mean sensor glucose, reduce highs and lows, and just as importantly reduce the work of living with diabetes."

Here is a recap of the major scientific data presentations on Medtronic innovation that took place at ATTD 2020:

Advanced Hybrid Closed Loop Scientific Data

- "Unannounced Meal Challenges in a Protected Free Living Environment Using the AHCL System"
- "Missed and Late Meal Boluses with Faster Acting Insulin Aspart (Fiasp®) vs. Insulin Aspart Using the Medtronic Advanced Hybrid Closed Loop System"

The advanced hybrid closed loop (AHCL) system is designed to combine automated basal (background) insulin delivery with automatic correction boluses. The AHCL system will also feature an adjustable target glucose as low as 100 mg/dL (5.5 mmol/L), the lowest amongst any automated insulin delivery system, for the first time. Compared with the MiniMed 670G system, the AHCL algorithm demonstrated an increased time spent in target glucose range of 70-180 mg/dL (3.9-10 mmol/L) and a reduction in post prandial excursions in feasibility studies.

Dosing insulin at mealtime can be a real challenge for people with diabetes, as they try to make sure they are giving the right amount of insulin, at the right time, for each meal. The combined automated basal and correction bolus of the AHCL system is designed to help accommodate for inexact carbohydrate counting or occasionally missed meal dose. The first study listed above assessed the effectiveness of the advanced SmartGuard™ auto-correction algorithm to overcome a missed pre-meal insulin dose, known as a bolus, using auto-correction, in meals with various carbohydrate totals.

In the study, 14 participants consumed pre-defined meals consisting of either 40, 60 and 80 grams of carbohydrates each day either with a bolus or no bolus. Preliminary data showed that overall glycemia in the four hours following meals consumed without a bolus demonstrated 70.7 percent time in range (70-180 mg; 3.9-10 mmol/L) and 3.26 percent time in hypoglycemia (<70mg; 3.9 mmol/L), compared to 86 percent time in range and 7.65 percent time in hypoglycemic range during the consumed meals with a bolus.

The study concluded that when meals containing 80 gram or less of carbohydrates are consumed without manually inputting the number of carbohydrates into the pump, the system provides safe glycemic control with over 70 percent time in range with minimal low sensor glucose readings.

The second study evaluated whether the use of Faster Acting Insulin Aspart (Fiasp®) may provide better post-meal glycaemia with late and missed boluses compared with insulin aspart. Adult pump-experienced participants with type 1 diabetes began using the advanced hybrid closed loop system and were randomly assigned Fiasp or insulin aspart over two stages (6-weeks duration each).

The study found a higher time in target range with Fiasp with missed bolus and a higher time in hypoglycemia range with late bolus. There were no major hypoglycemia or hyperglycemic excursions. Trends observed with a missed meal bolus suggest that Fiasp may offer advantages over insulin aspart though late meal-time bolus delivery remains a risk for hypoglycemia.

Extended Wear Infusion Set Scientific Data

- “Randomized Trial of Infusion Set Wear Duration: H-Cap Extended Wear Set vs. A Control Infusion Set”
- “Clinical Study of a New Extended Wear Infusion Set Design”

Longer wear infusion sets and less frequent set changes is an unmet need voiced by many individuals living with diabetes. Medtronic is advancing infusion set technology with the extended wear infusion set that is designed to last at least twice as long as current infusion sets, providing more time for infusion sites to rest and heal and to permit coordination of infusion set changes with CGM sensor changes. Individuals using the technology reported a reduction in user burden compared to use of current infusion sets.

Scientific data, including two new studies presented at ATTD, consistently demonstrate performance that is significantly better than the current infusion set technology. The most recent study demonstrated that infusion sets were still performing 80+ percent of the time at the end of the seven-day wear, which is equal or better to that observed for the current three-day infusion set at the end of 3-day wear.

This technology promises to bring highly differentiated innovation to the infusion set space, with the ultimate goal of minimizing the burden of infusion set changes with longer wear time.

“Real-Life Use and Performance of the MiniMed™ 670G System in Europe”
After the launch of the MiniMed 670G system in Europe, a performance assessment of real-life MiniMed 670G system use was conducted by reviewing voluntary uploads to CareLink™ Personal software from October 1, 2018 to August 14, 2019 from individuals using the system in Europe. The percentage of time spent in the various glycemic ranges, mean sensor glucose (SG) levels, and the associated Glucose Management Indicator (GMI, the calculated estimate of HbA1c) were assessed when SmartGuard Auto Mode was turned off (and the system was in manual mode) and when SmartGuard Auto Mode was turned on.

Data from 4,959 individuals living in 10 different countries were included in the analysis. When the SmartGuard Auto Mode feature was turned on, mean SG was 151 mg/dL (8.3 mmol/L), corresponding to a GMI of 6.9 percent (52 mmol/L). The time in range was 73.1 percent, time spent <70 mg/dL (3.9 mmol/L) was 2.3 percent, and time spent >180 mg/dL (10 mmol/L) was 24.7 percent. These outcomes were similar for each of the countries.

The real-world data shows that individuals using the MiniMed 670G system in Europe with the SmartGuard Auto Mode feature turned on achieved the internationally-recommended goals of glycemic control with time in range >70 percent and a GMI of <7 percent (<53 mmol/L), while minimizing hypoglycemia.

“Cost-Effective Analysis of Iterative Retrospective Professional Continuous Glucose Monitor (CGM) in People with Type 2 Diabetes in Portugal”
Medtronic conducted a retrospective analysis to evaluate the cost-effectiveness of professional continuous glucose monitoring (proCGM), also referred to as blinded or retrospective CGM, in people with type 2 diabetes from the data collected in the completed ADJUST study.

In the ADJUST study, individuals with type 2 diabetes who were already on insulin were provided a proCGM device at baseline, 4-, 8- and 12-months in the single-arm study. The use of the proCGM to make targeted therapy changes was associated with a reduction in HbA1c of -1.3 percent, from 9.4 percent (79mmol/mol) at baseline, to 8.1 percent (65mmol/mol) at 12 months. Overall, proCGM was associated with improved glycemic control and treatment satisfaction in people with type 2 diabetes with elevated HbA1c and already on insulin.

The retrospective analysis demonstrated that higher proCGM acquisition costs could be partially offset by reduction in complications over the patient’s lifetime. As such, ProCGM represents a potentially cost-effective management tool for people with type 2 diabetes in Portugal.

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.

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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