Medtronic News

Real-World Data on Over 4,000 Patients Using the Medtronic MiniMed™ 780G System Demonstrate Time in Range Mirroring Pivotal Trial

Results Demonstrate 76% Time in Range and 94% Time in Advanced Hybrid Closed Loop Mode

DUBLIN, June 2, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced real-world clinical outcomes for 4,120 individuals on the MiniMed™ 780G system, a small subset of those on the latest system today across nine countries in Europe. Data showed an average overall Time in Range of 76.2% and an overnight Time in Range of 83%, mirroring results from the pivotal trial. From an experience perspective, users remained in Advanced Hybrid Closed Loop (AHCL) mode, also referred to as the SmartGuard™ algorithm, for an average of 94% of the time, and an overall reduction in interactions required with the system demonstrated a more seamless experience than previous insulin pump systems.*

"It is extremely encouraging to see Medtronic advancing both clinical outcomes as well as the user experience through their latest MiniMed 780G system. It is clear that learnings from the launch of the world's first hybrid closed loop informed the design of this next-generation system," said Prof. Chantal Mathieu, endocrinologist at University Hospitals Leuven-KULeuven, Belgium. "We know that no two individuals with type 1 diabetes are the same, and that life gets in the way of managing diabetes perfectly. I am confident in this system's ability to do what a person with diabetes may not be able to do on their own by helping them minimize highs and lows, and ultimately live their lives less burdened by their diabetes."

The advanced SmartGuard algorithm in the MiniMed 780G system automates and personalizes the delivery of basal insulin by adjusting every five minutes, 24 hours a day. The latest system also includes an advanced algorithm that automatically corrects highs every five minutes through autocorrection dosing, in addition to protecting against lows.[1,2]. Autocorrection dosing is designed to correct highs that may result from not logging a meal (also known as bolusing), logging a meal late, or underestimating the carbohydrate content of the meal.

The MiniMed 780G system is the most advanced insulin pump system from Medtronic, currently approved for the treatment of type 1 diabetes in people age 7 to 80 years. The system enables the personalization of glucose goals with an adjustable target setting as low as 100 mg/dL (5.5 mmol/L) — lower than any other insulin pump system. The MiniMed 780G system is now available in 30 countries across Europe, the Middle East and Africa, and is currently being reviewed by the Food and Drug Administration (FDA) for approval in the U.S.

The real-world performance analysis aggregates information from individuals who uploaded their data to CareLink™ Personal from August 27, 2020 to March 3, 2021. A large majority of real-world users studied are achieving glycemic goals shared by major diabetes professional organizations, including:

- 79% of individuals had a Glucose Management Indicator (GMI) less than 7%, which mirrors the average A1C level that would be expected based on mean glucose.
- 77.3% of individuals had a Time in Range above 70%.
- 74.1% of individuals achieved both, a GMI less than 7% and a Time in Range above 70%.

In addition to the data reported from the overall cohort of 4,120 individuals, a smaller cohort of 812 individuals was analyzed, to compare the difference in outcomes as individuals move from pre-AHCL initiation (also referred to as open loop) to post-AHCL initiation. Within that cohort, individuals experienced an average Time in Range increase of 12.1% (from 63.4% to 75.5%), a 15.7 mg/dL or 0.9 mmol/L drop in mean sensor glucose (from 162.2 mg/dL to 146.5 mg/dL or 9.0 mmol/L to 8.1 mmol/L), and a 0.4% drop in GMI (from 7.2% to 6.8%) post AHCL initiation.

"The MiniMed 780G system is doing the job we built it to do – automatically correcting for high glucose when carbs are miscalculated or individuals forget to take extra insulin with their food," said Sean Salmon, executive vice president and president of the Diabetes business at Medtronic. "Our goal with all diabetes technology is to maximize clinical outcomes while making the solutions easier to use so that people can feel their best, reduce risk of complications and live their lives with diabetes in the background, instead of the forefront."

Time in Range

Clinical consensus regarding Time in Range means that a person living with diabetes should be in the recommended range of 70-180 mg/dL (3.9 – 10 mmol/L) for at least 70% of time to be well-controlled. This may increase the likelihood that short and long-term complications of this chronic disease can be avoided.

About the Diabetes Business 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 approximately 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

** Due to inherent study limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences.*

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.

[1] Carlson, A.L. et al. 97-P- Safety and glycaemic outcomes of the MiniMed™AHCL System in subjects with T1D. 80th ADA International Conference, June 2020, Chicago

[2] Collyns .O. et al. 199-OR- Improved glycaemic Outcomes with MiniMed™ AHCL Delivery. 80th ADA International Conference, June 2020, Chicago

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