Medtronic News

MiniMed™ 780G system demonstrates superiority over multiple daily injections with CGM for type 1 diabetes management at one-year in ADAPT study

A second randomized controlled trial sponsored by JDRF also demonstrates superiority of automated insulin pump as first-in-line therapy for children with type 1 diabetes

DUBLIN and BERLIN, Feb. 24, 2023 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced one-year data from the **ADAPT study** (n=82), the first multi-national randomized controlled study comparing the performance of the MiniMed™ 780G advanced hybrid closed loop system[1] (AHCL) against multiple daily injections (MDI) of insulin with an intermittently scanned CGM (isCGM). The study was done in adults (18 years of age and older) not meeting glycemic targets. The initial 6-month results, published in *The Lancet Diabetes & Endocrinology*, showed AHCL system users experienced a 27.6% absolute increase in Time in Range (TIR) and 1.4% reduction in HbA1C compared to those on MDI + isCGM without increased time in hypoglycemia. These results were even greater overnight with a TIR increase of 30.2%. At the close of the 6-month study period, all participants on MDI + isCGM crossed over to the MiniMed 780G system. At one year, these significant improvements were reproduced in this cross-over group and sustained in those that started on AHCL therapy at the start of the trial. These latest results were presented today at the 2023 Advanced Technologies & Treatments for Diabetes (ATTD) Conference in Berlin.

Significant Improvements in Clinical Outcomes with MiniMed 780G System

	MDI+isCGM group (switched to AHCL at 6 months)		
	MDI+isCGM	Switched to AHCL	
	At 6 months	At 12 months	Change (p-value)
Mean HbA1c *Primary Endpoint*	8.9 %	7.5 %	-1.4% (<0.0001)
Mean Time in Range (70 - 180 mg/dL) *Secondary Endpoint*	43.6 %	70.7 %	28.1% (<0.0001)

Long Term Maintained Clinical Outcomes with MiniMed 780G System

	AHCL group (remained on AHCL for 12 months)		
	AHCL	Remained on AHCL	
	At 6 months	At 12 months	Change (95% confidence interval)
Mean HbA1c *Primary Endpoint*	7.3 %	7.4 %	0.1 (-0.05 to 0.25)% *
Mean Time in Range (70 - 180 mg/dL) *Secondary Endpoint*	70.4 %	69.7 %	-0.7 (-2.1 to 0.7)% ✣

* Non-inferiority met (margin= 0.3); ✣ Non-inferiority met (margin= -6%).

"These results further strengthen the case for us to move beyond the CGM-first paradigm to ensure patients experience these well-established clinical benefits of automated insulin delivery earlier at diagnosis," said Ohad Cohen, M.D., Senior Global Medical Affairs Director, Medtronic Diabetes. "The MiniMed 780G system is taking care of users in ways that individuals just aren't able to with manual injections, even with the best of intentions, as there are so many variables that impact blood sugar levels on a daily basis."

Data from a second randomized controlled study sponsored by JDRF, called the **CLVer Trial,** (n=113) showed that in youth (7 to17 years old) with newly-diagnosed type 1 diabetes, early intensive management, including use of an automated insulin delivery system, resulted in superior Time in Range of 78% compared to 64% Time in Range in the standard-care group (real-time CGM without automated insulin delivery) at one year. The CLVer Trial results were presented in a late-breaking clinical trial

presentation at the ATTD Conference and concurrently published in the *Journal of the American Medical Association* (JAMA).

"There is a growing body of clinical evidence demonstrating the superiority of using automated insulin delivery systems as first-line treatment for type 1 diabetes rather than the standard stepwise approach of starting patients on a CGM first," said Jennifer McVean, MD, Senior Medical Affairs Director, Medtronic Diabetes. "These results demonstrate patient success earlier in the course of their disease and across the age spectrum. Considering this compelling evidence, we're committed to expanding access to our MiniMed 780G system so more people living with diabetes have an opportunity to improve short- and long-term health outcomes."

The Next Frontier in Therapy Management

Innovation of technology in type 1 diabetes has transformed the therapy and significantly improved outcomes and quality of life. Data presented today at ATTD addressed one of the remaining hurdles of delivering a closed loop system — the ability to manage complex meals and exercise. Prof. Amir Tirosh, Sheba Medical Centre Israel, presented studies that evaluated simplified meal announcement approaches with the MiniMed™ 780G system, confirming it was able to handle unannounced meals* up to 80 grams of carbohydrates, and that there was no deterioration in glycemic control when small amounts (up to 20 grams) of carbs were unannounced[2]. In addition, he presented data that precise carb counting, often seen as a prerequisite for access to advanced diabetes technology, is not as important as once thought.

Meal management has been cited as one of the most challenging aspects of diabetes management as today, individuals need to calculate the number of carbs they're consuming and input it into their pump so the correct amount of insulin can be delivered (called "announcing a meal"). The MiniMed™ 780G system was designed to anticipate real life needs where carb counts aren't always exact and meal doses are often missed. As Medtronic advances its SmartGuard™ algorithm towards a fully closed loop system, the company is evaluating the use of its MiniMed 780G system integrated with its proprietary Klue smartwatch app which leverages hand gestures detected by a smartwatch to announce meals to the pump with the goal of eliminating manual meal announcements.

Early data from a small single site study (n=17) showed users were able to maintain glycemic control similar to the current standard of care of manually announcing a meal in the pump and bolusing. The study evaluated the use of the MiniMed 780G system with the Klue app disabled while traditional carb counting and carb entry were completed at baseline. Following that, the app was enabled for five days, and carb counting was prohibited. This first study of this integrated system showed that it successfully handled test meals and drinks of varying caloric and carb size while maintaining good glycemic control with a Time in Range of 80.6% during the study period.

"Coupled with the real-world data we're seeing across 104 countries where it's commercially available, we're confident our system addresses a significant unmet need while delivering on the ease of use so many of our customers have asked for," said Que Dallara, EVP and President, Medtronic Diabetes. "We're committed to advancing our SmartGuard™ algorithm towards a fully closed loop system and these early results on our next-generation platform integrated with Klue are very promising."

The MiniMed 780G system integrated with the company's next-generation Guardian™ 4 Sensor is currently being reviewed by the Food and Drug Administration (FDA) for commercial approval and is currently investigational in the U.S.

* The MiniMed 780G system is optimized for use with meal announcement.

1. Carlson AL, et al. Safety and glycemic outcomes during the MiniMed™ Advanced Hybrid Closed-Loop system pivotal trial in adolescents and adults with type 1 diabetes. Diabetes Technol Ther.2022;24(3):178-189.
2. Tirosh et al. Abstract #517 Diabetes Technology & Therapeutics February 2020 (doi: 10.1089/dia.2020.2525.abstracts)

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

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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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