Medtronic News

Medtronic presents new data on MiniMed™ 780G system on fixed meal dosing and real-world Time in Range across wide variety of users

DUBLIN and SAN DIEGO, June 23, 2023 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, is presenting a robust collection of new clinical and real-world data on the MiniMed™ 780G system. These latest data sets, which evaluated the system across a wide range of users, including historically challenging younger patients, those not meeting glycemic goals, and individuals using a simplified meal announcement leveraging fixed carbohydrate amounts instead of exact carb calculations, found that the proprietary Meal Detection™ technology supported Time in Range outcomes that exceed consensus guidelines of 70 percent. Additionally, the system is helping reduce the percent of time spent in hyperglycemia in children and adults. These latest results were presented this weekend at the 83rd American Diabetes Association (ADA) Scientific Sessions in San Diego, CA.

Simplified Meal Announcements with the MiniMed™ 780G System

The first study by Dr. Goran Petrovski, MD, PhD, of Sidra Medicine, randomly assigned adolescents using the MiniMed™ 780G system (n=34) into two groups, with some entering a fixed pre-set number of carbs (small, average, or high) and some calculating a precise number of carbs for their meals. These individuals had lived with diabetes for at least one year and used multiple daily injections or pump therapy prior to the study. Results from the study, which were presented Friday in an oral podium presentation, showed those using the simplified (i.e., fixed) carb entry maintained international targets for glycemic control, including an A1c of 6.9% and Time in Range (TIR) of 72.7% (vs. 79.4% TIR in the precise entry group) over 6 months without system modification.[1] Additionally, the simplified entry group lowered their time above 250 mg/dL from 28.3% to 5.3% at six months (vs. 3.9% in the precise entry group). After 3 months, 88% chose to continue with the simplified meal management approach, which suggests user satisfaction with this less burdensome approach. These results suggest that reduced accuracy in carb counting can be overcome by the increased automated insulin delivery provided by the MiniMed™ 780G system, and that even those that cannot or do not input their carbs precisely can reach glycemic goals and reduce hyperglycemia.

"Many individuals with type 1 diabetes struggle with meal management with nearly 50% considering carb counting the most burdensome aspect of diabetes management.[2] Indeed, many frequently underestimate their carbs or forget to bolus and this has an adverse impact on clinical outcomes," said Dr. Petrovski. "This study shows that a simplified meal management approach with the MiniMed™ 780G system helped users maintain glycemic targets while providing forgiveness for inexact carb counts. Clearly there's more runway for simplification of diabetes management with this system and it's promising for the many patients struggling with meal management."

Strong Real-World Performance in Children

An analysis of real-world evidence of children ≤ 15 years inEurope and Latin America (n=3,543) using the MiniMed™ 780G system with recommended settings of 100 mg/dL and 2-hour active insulin time (AIT) demonstrated a Time in Range of 78% (Table 1).[3] A separate analysis of real-world evidence of children ≤ 15 years inEurope (n= 2,516) demonstrated improved glycemic performance in SmartGuard™ technology regardless of baseline glycemic control.[4] The group with the lowest Time in Range (poorest glycemic control) prior to SmartGuard™ technology, had the largest increase of 23.3% in Time in Range, while patients with the best metabolic control in SmartGuard™ technology achieved 80.6% Time in Range (Table 2). Additionally, this increase in Time in Range was seen with less effort as evidenced by fewer user-initiated boluses, indicating decreased patient burden.

Table 1: Real-World Evidence of Pediatric Users in Europe, Middle East and Africa & Latin America (using Recommended Settings)				
	Europe, Middle East and Africa		**Latin America**	
	All Users ≤ 15 years	**With Recommended Settings**	**All Users ≤ 15 years**	**With Recommended Settings**
Time in SmartGuard™ technology	92.7 %	94.6 %	93.5 %	94.9 %
Time in Range	73.9 %	78.9 %	74.2 %	78.2 %
Time Above Range (> 180 mg/dL)	22.9 %	17.5 %	23.0 %	18.9 %

Table 2: Real-World Evidence of Pediatric Users in Europe (using Recommended Settings)								
	Group 1 *(Lowest glycemic control at initiation)*		**Group 2**		**Group 3**		**Group 4** *(Highest glycemic control at initiation)*	
	Base line	**With MM780G**	**Baseline**	**With MM780G**	**Baseline**	**With MM780G**	**Baseline**	**With MM780G**
Time in SmartGuard™ technology	-	89.9 %	-	91.5 %	-	93.2 %	-	91.9 %
Time in Range	41.0 %	64.3 %	55.5 %	69.9 %	65.7 %	73.1 %	79.8 %	80.6 %
Time Above Range	57.2 %	33.3 %	42 %	27 %	30.9 %	23.8 %	16.6 %	16.5 %
User-initiated boluses/day	6.3	4.9*	6.6	5.7*	7.0	5.9*	6.7	6.3*
Insulin Units Delivered by Auto Correction	14.4	18.0	12.3	14.5	12.0	13.3	10.2	10.9

*Baseline vs post-AHCL number of daily boluses comparison ($p<0.0001$).

Medtronic Extended Infusion Set Real-World Data

For the first time, real-world data on the Medtronic Extended Infusion™ Set was presented (n=108) and the analysis showed an

average infusion set wear time of 6.74 days. Almost half (48.2%) of the individuals evaluated wore the set for 7 days. This real-world data mirrors the results from the U.S. pivotal trial and is delivering a reduced user burden through less frequent infusion set changes.

"We're committed to pushing simplification of diabetes management as far as we can and are heartened to see the impact our MiniMed™ 780G system is having on both clinical and quality of life outcomes as evidenced by our randomized controlled ADAPT study and the growing body of real-world evidence from around the world," said Que Dallara, EVP and President of Medtronic Diabetes. "With each advancement, we're working to reduce more of the burden that this disease demands and will continue to innovate to make life easier for those we have the privilege to support."

About Medtronic Diabetes (www.medtronicdiabetes.com)

Medtronic Diabetes is on a mission to alleviate the burden of diabetes by empowering individuals to live life on their terms, with the most advanced diabetes technology and always-on support when and how they need it. We've pioneered first-of-its-kind innovations for over 40 years and are committed to designing the future of diabetes management through next-generation sensors (CGM), intelligent dosing systems, and the power of data science and AI while always putting the customer experience at the forefront.

About the MiniMed™ 780G system (www.medtronicdiabetes.com/780G)

The MiniMed™ 780G system is the first system in the world featuring Meal Detection™ technology,* which provides automatic adjustments and corrections† to sugar levels every 5 minutes§. The system provides insulin to help account for when users occasionally forget to bolus or underestimate the number of carbs in their meal and features the lowest glucose target setting (as low as 100 mg/dL) in any automated insulin pump on the market,§ which more closely mirrors the average glucose of someone not living with diabetes. The MiniMed™ 780G system is approved in the U.S. for individuals with type 1 diabetes, 7 years and above.

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.

*Taking a bolus 15 – 20 minutes before a meal helps to keep blood sugar levels under control after eating.
† Refers to auto correct, which provides bolus assistance. Can deliver all auto correction doses automatically without user interaction, feature can be turned on and off.
§ Refers to SmartGuard™ feature. Individual results may vary.
**The extended wear infusion set can be worn for up to 7 days. Current infusion sets are recommended for up to 3 days of wear.
‡ Fingersticks required in manual mode & to enter SmartGuard™. If symptoms don't match alerts & readings, use a fingerstick. Refer to user guide. Pivotal trial participants spend avg of > 93% in SmartGuard™.

1. Auto corrections help make up for imprecise carb counts.

2. Medtronic data on file. 25-minute survey, N= 498 T1D individuals inGermany, Japan, US, Brazil, August 2019.
3. "Higher Time in Range Demonstrated in Children Using Intensive Advanced Hybrid Closed-Loop (AHCL) System Settings" – poster presentation (1120-P) by Jen McVean, M.D., pediatric endocrinologist, senior director, medical affairs, Medtronic Diabetes on Monday, Jun. 26 at 11:30 a.m. PDT
4. "Improved Glycemic Control with Less Effort during Real-World MiniMed™ 780G Advanced Hybrid Closed-Loop (AHCL) System Use by Children with T1D" – poster presentation (1119-P) by Jen McVean, M.D., pediatric endocrinologist, senior director, medical affairs, Medtronic Diabetes on Monday, Jun. 26 at 11:30 a.m. PDT

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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