Medtronic InPen™ Real-World Data and Extended Infusion Set* Pivotal Trial Results Demonstrate Strong Clinical Outcomes and Positive User Experience

Data Were Presented at the American Diabetes Association 81st Scientific Sessions

DUBLIN, June 28, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced key clinical data from the virtual 81st annual American Diabetes Association Scientific Sessions. The presentations illustrated increases in Time in Range when using an InPen™ smart insulin pen, safety of an extended-wear infusion set that lasts up to 7 days, and patient satisfaction with the longer-wear infusion set.

InPen Smart Insulin Pen Data

Medtronic presented real-world clinical results that compared glycemic outcomes for 1,736 individuals before and after using the InPen smart[1] insulin pen for 90 days with a glucose monitor (CGM). Data showed an increase in Time in Range of 2.3% for people whose glucose management indicator (GMI) was >8% and an increase of 5% Time in Range for people whose GMI was >9.5%. In both groups, people did not experience any increase in Time Below Range[2] (hypoglycemia) during the study period.

Using InPen smart insulin pen also provided improved insulin dosing decision support for those in the study as demonstrated by fewer total doses per day with simultaneously improved glycemic control. The average daily insulin bolus frequency decreased (from 3.7 to 3.6/day and 3.3 to 3.2/day, respectively, for each group) and total rapid acting daily dose of insulin increased (from 26.29 to 27.19 u/day and 27.57 to 29.24 u/day, respectively, for each group). This real-world performance analysis aggregates information from individuals who uploaded their data from January 2018 to October 2020. A minimum of 30 days of CGM data pre- and post-InPen start were required to be part of the analysis.

"Smart insulin pens that automatically track insulin doses and calculate active insulin are emerging as important advances in diabetes management technology because they increase the amount of time spent in the preferred glucose range without increasing hypoglycemia," said Dr. Anders Carlson, medical director of the Park Nicollet International Diabetes Center (IDC) in Minneapolis, Minn. "It's encouraging to see that positive clinical gains are possible with the use of consumer-friendly diabetes technology, such as InPen, that makes it simple for patients to track insulin dosing, calculate doses and receive reminders and other decision support that allows them to manage their diabetes more effectively without adding a lot of complexity."

Medtronic Extended Infusion Set Data

Medtronic also presented U.S. pivotal trial data on the Medtronic Extended infusion set, the first and only infusion set that can be worn for up to seven days. The study evaluated the safety and performance of 259 individuals aged 18 to 80 who wore traditional 2- or 3-day infusion sets with the MiniMed™ 670G system for two weeks followed by twelve consecutive wears of the Medtronic Extended infusion set. The study showed no significant increase in total daily dose of insulin. This indicates that the Medtronic Extended infusion set delivers insulin successfully throughout the seven-day wear of the infusion set. In addition, there were no severe adverse events observed.

During the pivotal study, the same group of patients compared their experience of wearing a 2- or 3-day set to wearing the new 7-day Medtronic extended infusion set. Overall, patients preferred the longer-wear set, rating it higher on ease of insertion, comfort of wear, duration of wear, time required to change infusion set and convenience.

"For decades, insulin infusion sets needed to be changed every two to three days. So, the development of an extended infusion set that can be worn for up to seven days represents a significant improvement in the patient experience," said Bruce Buckingham, M.D., emeritus professor of pediatrics and endocrinology at Stanford. "The pivotal trial demonstrated the safety of the new infusion set as well as increased satisfaction from being able to wear it longer. Alleviating the burden of changing infusion sets every two to three days is a very meaningful improvement in the overall pump experience. This important innovation in the infusion set will make insulin pump therapy feel easier for many patients."

* In the United States, Medtronic Extended infusion set is limited to investigational use only and not approved for sale, while in Europe it is already CE marked.

Definitions

- **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.

- **Glucose Management Indicator (GMI)**– GMI mirrors the A1C level expected based on average glucose measured using continuous glucose monitoring (CGM) values.
- **InPen** - The InPen is the first and only smart insulin pen that's integrated with real-time CGM via one convenient smartphone app. The smart multiple daily injection (MDI) system automatically records insulin doses, tracks active insulin, and recommends mealtime and correction doses. By combining the InPen system with the Guardian™ Connect CGM system, individuals have access to everything they need to manage their diabetes in one place. Rather than switching between apps, users will have the ability to see real-time glucose readings and alerts as well as insulin dose information in real-time, in one view — making it easier to make informed dosing decisions to manage their glucose levels.
- **Medtronic Extended Infusion Set** - The Medtronic Extended infusion set is the first and only infusion set that can be worn for up to 7 days. The innovative design of the Medtronic Extended infusion set, which is designed and manufactured in collaboration with Unomedical, leverages advanced materials that help reduce insulin preservative loss and maintains insulin flow and stability.

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] Smart insulin pens connect to a mobile app to provide dosing calculations, reminders and CGM system integration.
[2] Time Below Range is time spent below 70 mg/dl.

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https://news.minimed.com/2021-06-28-Medtronic-InPen-TM-Real-World-Data-and-Extended-Infusion-Set-Pivotal-Trial-Results-Demonstrate-Strong-Clinical-Outcomes-and-Positive-User-Experience