Medtronic Receives FDA Approval of New Pediatric Indication for the MiniMed(TM) 670G Hybrid Closed Loop System in Children Ages 7-13

(GLOBE NEWSWIRE via COMTEX) --DUBLIN- June 21, 2018 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that the U.S. Food and Drug Administration (FDA) has approved the use of the MiniMed(TM) 670G system in patients with type 1 diabetes seven years of age and older. This newest system by Medtronic features the company's most advanced SmartGuard(TM) technology and most accurate CGM - the Guardian Sensor 3 - which work together to automate the delivery of a personalized amount of basal insulin every five minutes based on sensor glucose values. The system constantly self-adjusts to help avoid highs and lows, allowing patients to spend more Time in Range (the percentage of time spent in the optimal glycemic range of 70-180 mg/dL).

"The MiniMed 670G system is the most advanced insulin delivery system on the market today and proven to effectively manage type 1 diabetes," said Dr. Jennifer Sherr, a pediatric endocrinologist at Yale New Haven Children's Hospital's diabetes clinic and an associate professor of pediatric endocrinology at the Yale School of Medicine. "In the pediatric clinical trial, there was an increase in Time in Range (70-180mg/dL) for sensor glucose values and a reduction in time spent in both hypoglycemia and hyperglycemia, which is compelling in light of the well-known challenges associated with maintaining stable glucose levels throughout the day and night in this younger age group."

FDA approval was based on positive results from a pediatric clinical trial, which demonstrated the safety of the MiniMed 670G system in this younger patient population.1 Data was analyzed from 105 children between seven and 13 years of age with type 1 diabetes during a two-week baseline period in open-loop mode (traditional pump therapy), followed by a three-month in-home study period with the hybrid-closed loop (SmartGuard Auto Mode) enabled. The results showed the percentage of Time in Range increased from 56.2 percent to 65.0 percent. A1C levels were also reduced from 7.9 percent to 7.5 percent. There were no incidences of diabetic ketoacidosis (DKA) in the study phase in Auto Mode and no severe hypoglycemic or serious device-related adverse events were reported. Almost all children continued to use the pump after the study concluded.

"We are thrilled to be able to offer this advanced insulin management system to younger patients and their caregivers to help alleviate some of the burden associated with this unrelenting disease and to improve their quality of life" said Francine Kaufman, M.D., chief medical officer and vice president of global regulatory, medical and clinical affairs of the Diabetes Group at Medtronic. "This expanded age indication provides an important new treatment option for pediatric clinicians and parents of young children with type 1 diabetes, and further demonstrates our strong commitment to improving outcomes across the full diabetes care continuum."

"As parents, we feel so much more at ease knowing the Medtronic MiniMed 670G system is automatically reacting to our son's active lifestyle and monitoring him 24 hours a day for any lows or highs," said Karen and Keith, whose nine-year-old son Mason is on the MiniMed 670G system. "This has translated to better control for Mason, fewer sleepless nights for our family, and more time for our son to lead a normal life."

The MiniMed 670G system is commercially available for immediate shipment to patients interested in transitioning to the system. A multimedia press kit for the MiniMed 670G system can be accessed at the following link: http://bit.ly/2rk7BhW.

Time in Range

Time in Range refers to the percentage of time people with type 1 diabetes spend in the optimal glycemic range of 70-180 mg/dL. The goal with diabetes management is to increase time spent in this healthy range and to minimize high and low sugar levels, which can lead to both immediate and long-term complications such as damage to blood vessels - increasing the risk of coronary artery disease, heart attack, and stroke. Damage to blood vessels can also lead to loss of vision, kidney disease, and nerve problems. Increasing the "Time in Range" over the long-term can best be accomplished by using advances in diabetes therapies, like the MiniMed 670G system with SmartGuard technology, that automates basal insulin delivery.

MiniMed(TM) 670G Pediatric User

Click the thumbnail above for a larger image.

Click the video above to view or click here to view it on YouTube.

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 85,000 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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1 Data on file.

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https://stage.mediaroom.com/minimed_mr/2018-06-21-Medtronic-Receives-FDA-Approval-of-New-Pediatric-Indication-for-the-MiniMed-TM-670G-Hybrid-Closed-Loop-System-in-Children-Ages-7-13