Medtronic Requests Approval of Non-Adjunctive Labeling from FDA

July 23, 2019

DUBLIN, July 23, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, services and solutions, today announced its Premarket Approval (PMA) submission to the U.S. Food and Drug Administration (FDA) requesting approval for non-adjunctive labeling for its Guardian™ Sensor 3, as part of the MiniMed™ 670G system. If the FDA approves a sensor with non-adjunctive labeling, it means that a sensor is accurate enough to be used to calculate an insulin dose for meals and to correct high glucose levels. Since Medicare requires a non-adjunctive label for sensor reimbursement, if approved, this labeling could broaden patient access by allowing for Medicare coverage of the world's first and still the only commercially available hybrid closed loop system.

The MiniMed 670G system is being used by more than 180,000 people today[1], and the associated data on nearly 8 million patient days[2] shows an average Time in Range of 71% across all age groups, which mirrors the pivotal trial data published in the *Journal of the American Medical Association* (JAMA). Importantly, the clinical data meets the goals outlined in the Time in Range consensus guidelines recently published at the American Diabetes Association meeting[3]. Overnight, when many individuals with diabetes worry about lows, MiniMed 670G system data shows Time in Range of 78% in a real-world environment, with less than 0.5% in the low ranges <54 mg/dL[4].

The SmartGuard™ technology in the MiniMed 670G system automates and personalizes the delivery of basal insulin 24 hours a day and is the only commercially available technology in the world that proactively drives increased Time in Range by consistently guiding to the target of 120 mg/dL throughout the day-the lowest range offered in an automated insulin pump system.

"We are very proud of the clinical outcomes our MiniMed 670G system is delivering to patients on our system and we're very pleased to see these results sustained in the real-world where many factors put the system to the test," said Dr. Robert Vigersky, chief medical officer, Global Medical and Clinical Affairs for the Diabetes Group at Medtronic. "Our goal now is improving usability and the overall patient experience with the system by increasing automation, and seeking expanded access to seniors covered under Medicare plans."

The company's submission for non-adjunctive coverage follows the launch of the enhanced Guardian™ Link 3 transmitter earlier this year, which improved the patient experience on the system by reducing the number of system alarms by 60%[5], and allowing patients to spend an additional 2.2 hours per day utilizing the SmartGuard technology in Auto Mode[2], which automatically regulates basal insulin throughout the day and night[6].

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 90,000 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. Based on shipped units globally.

[2] Refers to Time in Range of 71% obtained from data from CareLink™ software uploads in the US from March 2017 to March 2019; patient days = 7,984,915.

[3] Battelino T, Danne T, Bergenstal R, et al. Clinical targets for continuous glucose monitoring data recommendations from the international consensus on time in range. Diabetes Care. 2019. https://doi.org/10.2337/dci19-002.

[4] Data obtained from CareLink™ software uploads in the US from March 2017 to March 2019; patient days = 7,984,915. Overnight is considered 12am-6am.

[5] All data is taken from voluntary CareLink Uploads (as of December 1st 2018 through March 1st 2019). Data collected 30 days before and after occurrence of new transmitter ID . At least 7 days of data required for old & new transmitter . BG Loop definition: AM exit following 3+ SI failures and/or 3+ BG requests within 100 min. BG Required Alerts indicate: SI failure alerts. (n=2,419 users).

[6] Refers to AutoMode. Some user interaction required. Individual results may vary.

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