Medtronic News

Medtronic Receives CE Mark for MiniMed(TM) 670G Hybrid Closed Loop System

GLOBE NEWSWIRE via COMTEX) --DUBLIN - June 25, 2018 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received CE (Conformité Européenne) Mark for the MiniMed(TM) 670G hybrid closed loop system - the first and only system to automate and personalize the delivery of basal insulin 24 hours a day1. The system is CE Mark approved for the treatment of people with type 1 diabetes 7 years of age and older with ongoing studies to expand the indication to additional patient populations.

"We're proud to introduce our most advanced SmartGuard Auto Mode algorithm outside of the United States, which not only helps to prevent lows but works to drive Time in Range - a most important measure of the effect of diabetes management on a patient's glucose levels - by decreasing time in hyperglycemia," said Alejandro Galindo, president of the Advanced Insulin Management division within the Diabetes Group at Medtronic. "The MiniMed 670G system advances our ability to automatically suspend and resume insulin delivery to the next level by automating self-adjusting basal insulin delivery every 5 minutes based on sensor glucose values - providing the most advanced algorithm available to deliver leading clinical outcomes."

The company's most advanced SmartGuard(TM) technology and most accurate2 continuous glucose monitor (CGM) - the Guardian(TM) Sensor 3 - work together to self-adjust basal insulin delivery to offer protection against both highs and lows, helping to improve Time in Range (the percentage of time spent in the optimal glycemic range of 70-180 mg/dL or 3.9-10 mmol/L)3,4. SmartGuard technology is the only smart algorithm that can adapt to fluctuating glucose levels and automatically self-adjust background insulin delivery to stabilize them. This advanced algorithm mimics some of the functions of a healthy pancreas and is the only technology in the world that proactively drives an increase in Time in Range - addressing both highs and lows. The system also exclusively features the CONTOUR®NEXT LINK 2.4 blood glucose monitoring system from Ascensia Diabetes Care.

"We have seen that this innovation offers great promise for better glucose control and improved quality of life for those living with Type 1 diabetes," said Pratik Choudhary, M.D., senior lecturer and consultant in diabetes at King's College London. "The ability of the MiniMed 670G system to stabilize glucose levels automatically is an important advancement, and I look forward to introducing it to my patients in Europe."

Medtronic will begin commercial release of the MiniMed 670G system in select countries in Europe in the autumn of 2018, subject to local regulatory requirements.

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 (3.9-10 mmol/L). The goal with diabetes management is to increase time spent in this healthy range and to minimize high and low blood glucose 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 be accomplished by using advances in diabetes therapies, like the MiniMed 670G system with SmartGuard technology, that automates basal insulin delivery.3,4

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 86,000 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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Ascensia Diabetes Care and Contour are trademarks and/or registered trademarks of Ascensia Diabetes Care Holdings AG.

For detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events, please consult the device manual. For further information, contact your local Medtronic representative.

1 Iturralde E, et all. The Diabetes Educator. 2017; 43(2):223 - 232.

2 Christiansen M, et al. Diabetes Technol Ther. 2017; 19(9): 1-11.

3 Bergenstal, R. M. et al. Jama. 2016; 316 (16): 1407 - 1408.

4 Garg SK et al. Diabetes Technol Ther. 2017 Mar;19(3):155-163.

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