Medtronic News

Medtronic Receives FDA Breakthrough Designation for Developing Personalized Closed Loop Insulin Pump System for Diabetes Management

GLOBE NEWSWIRE via COMTEX) --DUBLIN - February 19, 2019 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its Personalized Closed Loop (PCL) insulin pump system, currently in development. The PCL technology is designed to automate insulin delivery in a way that is real-time, personalized and adapts to the user. The system will also provide insights and predictive diagnostics unique to the individual, with a goal of dramatically simplifying diabetes management for the patient. The recent acquisition of Nutrino Health and their expertise in nutrition data science will play a key role in the accelerated development of this breakthrough technology.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

"We are very excited to receive the Breakthrough Device designation from the FDA as it will help us deliver this broadly anticipated innovation to patients much sooner than expected," said Alejandro Galindo, president of the Advanced Insulin Management division within the Diabetes Group at Medtronic. "We believe the Personalized Closed Loop system will be transformational for diabetes management, and the personalized nature of the algorithm clears the path to a true closed loop system. We have a long history of partnership with the FDA and look forward to another successful collaboration with the Agency to bring this important innovation to patients."

"It is incredibly rewarding as an endocrinologist to see this novel closed loop innovation in development as it holds significant promise for simplifying diabetes management and taking on much more of the work on behalf of the patient," said Dr. Kevin Kaiserman, pediatric endocrinologist, SoCal Diabetes. "I'm pleased to see the FDA continuing to support the acceleration of important therapeutic options that address true unmet needs and commend them for these efforts."

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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