Medtronic News

Medtronic Approved to Start Pivotal Trial to Evaluate New Extended Wear Infusion Set

Experimental Infusion Set Aims to Address Patient Burden with Comfort and Convenience Features for Insulin Pump Therapy

DUBLIN, Aug. 16, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that it received investigational approval from the U.S. Food and Drug Administration (FDA) to proceed with a pivotal trial for a new extended wear infusion set. The goal of the study will be to collect clinical data to support the use of the extended wear infusion set for up to seven days – more than twice the length of time that any infusion set can currently be used. The multi-center, non-randomized, prospective single arm study will enroll up to 150 subjects, aged 18 to 80, with type 1 diabetes on insulin pump therapy.

Infusion sets allow people on insulin pump therapy to deliver insulin under the skin to maintain healthy blood glucose levels. Current generation infusion sets must be changed every two to three days. Using proprietary technology and developed in partnership with ConvaTec's Unomedical subsidiary, this new infusion set aims to extend patient wear time by using new adhesive technology as well as maintaining insulin stability. An extended wear infusion set could solve a key unmet need in insulin pump therapy by reducing the time and effort currently spent on changing infusion sets. When used with Medtronic insulin pump systems that include 7-day continuous glucose monitors, this new infusion set could allow coordination of changing of the infusion set and sensor at the same time, a feature that would address making insulin pump systems more convenient to use.

"I would love for my son to spend less time thinking about his diabetes and more time living his best life," said Dani Labriola whose son uses the MiniMed™ 670G system to manage his diabetes. "Changing his set once per week instead of 2-3 times would take away some of that burden and would make a difficult disease easier."

In the trial, users of the MiniMed 670G system (i.e., pump, sensor and transmitter) will wear each infusion set for up to seven days. The initiation of this trial follows Medtronic's receipt of an Investigational Device Exemption (IDE) approval from the FDA.

"There have been significant advances made in the three-plus decades with insulin pumps and continuous glucose monitoring (CGM). However, we are still stuck with having patients change the insulin delivery sets every 2-3 days whereas most CGMs are now used longer," said Satish Garg, M.D., professor of Medicine and Pediatrics and director of the Adult Diabetes Division of Barbara Davis Center of the University of Colorado. "It is time for an infusion set to extend wear to a week and beyond. This is long overdue and will likely improve quality of life for patients on insulin pumps, and many more patients may accept insulin pump as an option."

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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