Medtronic News

The Journal of the American Medical Association Publishes Medtronic's Hybrid Closed Loop System Pivotal Trial Results

DUBLIN - September 15, 2016 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the publication of its Hybrid Closed Loop system pivotal trial results in the *Journal of the American Medical Association (JAMA).* The data presented the safety of the system and showed that patients on the therapy experienced less glycemic variability, more time in the target range, less exposure to hypoglycemia and hyperglycemia, and reduced A1c compared to baseline data using sensor augmented pumps.1 The data was concurrently presented at the 52nd annual meeting of the European Association for the Study of Diabetes (EASD) in Munich, Germany.

"This large at-home study demonstrated that participants with Medtronic's Hybrid Closed Loop system experienced improved glucose control and did not demonstrate any safety issues; during the study phase, there were no episodes of severe hypoglycemia or ketoacidosis in patients with type 1 diabetes on the therapy," said Richard M. Bergenstal, M.D., principal investigator of the study and executive director of the International Diabetes Center in Minneapolis. "The data is compelling and shows that the system's ability to automate insulin dosing 24 hours a day has the potential to impact patients' lives in a very meaningful way - particularly at night when it's most challenging to maintain target blood glucose levels."[i]

Medtronic's Hybrid Closed Loop study is the first pivotal U.S. trial of closed loop technology, and the largest and longest at-home closed loop study with over 12,000 days included in the evaluation. The system is designed to automate basal insulin delivery to maximize the time glucose levels are in a healthy range throughout the day and night. This multicenter study enrolled 124 people with type 1 diabetes >=14 years of age at 10 centers (nine in the U.S. and one in Israel).1 Participants in the study were required to enter their mealtime carbohydrates and exercise information, and periodically calibrate the sensor.

"We are pleased with the progress we have made in automating basal insulin delivery and that each new advancement in our phased approach delivers increased automation and greater peace of mind by helping to simplify diabetes management," said Alejandro Galindo, president of the Intensive Insulin Management Diabetes business at Medtronic. "We are committed to developing meaningful solutions like this to enable greater freedom and better health so people with diabetes and their caregivers can spend less time managing the disease and more time enjoying life's everyday moments."

Medtronic submitted a Pre-Market Application (PMA) for the Hybrid Closed Loop system to the U.S. Food and Drug Administration in June 2016, for the evaluation of safety and efficacy of the system. The system is investigational and not approved for commercial sale anywhere in the world.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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 Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA*. Published on-line ahead of print September 15, 2016 at jama.com (Online First).

[i] Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA*. Published on-line ahead of print September 15, 2016 at jama.com (Online First).

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