Medtronic News

Medtronic Receives FDA Approval for Trial Evaluating New Energy Source with Pulsed Electric Fields to Treat Atrial Fibrillation

Investigative Technology Designed to Interrupt Irregular Pathways in the Heart

DUBLIN, Jan. 23, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced that it received approval from the U.S. Food and Drug Administration (FDA) to proceed with an investigational device exemption (IDE) trial to evaluate the safety and effectiveness of the PulseSelect™ Pulsed Field Ablation (PFA) System, a new technology that uses pulsed electric fields to treat atrial fibrillation. First procedures in the trial were performed in December 2019 by Bradley Wilsmore, M.D., at John Hunter Hospital, New Lambton Heights, NSW, Australia and in January by Atul Verma, M.D., the principal investigator (PI) for the study, at Southlake Regional Health Centre in Newmarket, Canada.

PFA uses pulsed electric fields to ablate or create lesions and scar tissue to interrupt irregular electrical pathways in the heart and the triggers of atrial fibrillation. However, unlike traditional methods of ablation that heat the tissue (radio frequency) or cool the tissue (cryo) to ablate, PFA is non-thermal and selectively targets cardiomyocytes (heart muscle cells) while avoiding other types of tissue.

“This study will evaluate a new energy source that may treat atrial fibrillation and potentially address the risks that have been associated with other ablation technologies, such as unintended tissue damage,” said Verma. “The rigorous pre-clinical research to get us to these first procedures has been impressive and we are excited to support the development of more clinical evidence.”

In September 2018, Medtronic was granted Breakthrough Device designation from the FDA for the PFA technology for the treatment of drug refractory recurrent symptomatic atrial fibrillation. Worldwide, the PFA system is investigational and not approved for sale or distribution.

PULSED AF is a prospective, multi-center, non-randomized, unblinded and worldwide study that will enroll patients who will be treated with the Medtronic PulseSelect PFA System.

“As a global leader in the treatment of cardiac arrythmias, Medtronic is constantly evaluating new and existing therapies to better meet the needs of patients and the physicians who care for them,” said Rebecca Seidel, vice president and general manager in the Atrial Fibrillation Solutions division, which is part of the Cardiac and Vascular Group at Medtronic. “The PULSED AF study is another example of our commitment to meaningful innovation and a major step forward in the development of a diverse set of therapy options for atrial fibrillation patients.”

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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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