

Medtronic Begins Pilot Study of Investigational Extravascular ICD System

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(GLOBE NEWSWIRE via COMTEX) --Chronic Study Evaluating New ICD System Designed to Deliver Pacing and Defibrillation Therapy Via a Lead Placed Under the Sternum, Outside the Heart and Veins

DUBLIN - August 9, 2018 - Medtronic plc (NYSE:MDT) today announced the start of a pilot study of its investigational Extravascular Implantable Cardioverter Defibrillator (EV ICD) system, in which a lead is placed outside of the heart and veins to deliver lifesaving defibrillation and antitachycardia pacing therapy all in one system, with a device size similar to transvenous ICDs. The first patient implant was performed at Christchurch Hospital in New Zealand, representing the first intended long-term patient use of the Medtronic EV ICD system. The EV ICD system is investigational and not approved for sale or distribution.

"The Medtronic EV ICD system has the potential to deliver the benefits of traditional ICDs while eliminating the risks that can occur when leads are implanted inside the veins and heart," said Ian Crozier, M.D., Department of Cardiology, Christchurch Hospital, Christchurch, New Zealand, and principal investigator (PI) in the Medtronic Extravascular ICD Pilot Study. "We are incredibly pleased to contribute to this important research that will serve as a key step in establishing the safety and efficacy of this new approach."

The pilot study will assess the Medtronic EV ICD system in 20 patients at four sites: Christchurch Hospital (Dr. Crozier); Austin Health in Heidelberg, Australia (PI: David O'Donnell, M.D.); MonashHeart in Clayton, Australia (PI: Emily Kotschet, M.D.); and The Prince Charles Hospital in Brisbane, Australia (PI: Haris Haqqani, M.D.). After implantation of the system, patients and their devices will be routinely checked to assess safety and device performance.

"As a global leader in ICD innovation, Medtronic is developing new approaches for delivering lifesaving ICD therapy," said Mike Marinaro, vice president and general manager of the Cardiac Rhythm Management business, which is part of the Cardiac Rhythm and Heart Failure division at Medtronic. "This pilot study is a significant step forward in our EV ICD clinical development program, as we aim to offer patients the therapies of a traditional transvenous ICD, but without leads implanted in the heart."

The Medtronic EV ICD system is intended to provide the benefits of traditional transvenous ICDs including lifesaving defibrillation therapy, antitachycardia pacing to painlessly terminate arrhythmias, as well as post-shock pacing to protect from sudden cardiac death; and bradycardia pacing to address abnormally slow heart rates. It also is the same size (33 cc) and shape, and is expected to have similar longevity as traditional ICDs, but without any leads (thin wires) in the veins or heart. The investigational EV ICD device is implanted in the left mid-axillary region below the left armpit, and the newly designed lead is placed under the sternum (breastbone). New procedure tools guide the delivery of the system.

Medtronic research teams developed the EV ICD System and have completed multiple early research and acute feasibility studies using the system components, including the ASD1 (Acute Sensing and Defibrillation), SPACE2 (Substernal Pacing Acute Clinical Evaluation) and ASD23 studies.

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. Medtronic 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 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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2 Sholevar DP, Tung S, Kuriachan V, et al. Feasibility of extravascular pacing with a novel substernal electrode configuration: The Substernal Pacing Acute Clinical Evaluation Study. Heart Rhythm. Published online 29Nov2017. DOI: <http://dx.doi.org/10.1016/j.hrthm.2017.11.030>

3 Boersma, LVA. Feasibility of Extravascular Pacing, Sensing And Defibrillation From A Novel Substernal lead: The Acute Extravascular Defibrillation, Pacing And Electrogram (ASD2) Study. Presented Heart Rhythm Society Scientific Sessions, May 11, 2018.

Contacts:

Tracy McNulty
Public Relations
+1-763-526-2492

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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