Medtronic News

Medtronic Reveals Results of First-In-Human Study for Investigational Extravascular ICD System

Company to Proceed with Plans for Future Pivotal Study of New ICD System

DUBLIN and SAN FRANCISCO – May 11, 2019 – Medtronic plc (NYSE:MDT) today announced findings from 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 anti-tachycardia pacing therapy in one system, with a device the same size as traditional, transvenous ICDs. Results from the pilot study were presented during a late-breaking session at Heart Rhythm 2019, the Heart Rhythm Society's 40th Annual Scientific Sessions.

The Extravascular ICD pilot study, which represents the first-in-human chronic (long-term) use of the investigational, first-generation system, showed that the new system can be implanted with no major complications, and can sense, pace and defibrillate the heart. *The EV ICD system is investigational worldwide and not approved for sale or distribution.*

“I am very encouraged by our pilot experience using the Medtronic EV ICD system in patients out to three months,” said Ian Crozier, M.D., Department of Cardiology, Christchurch Hospital, Christchurch, New Zealand, and principal investigator (PI) in the pilot study. “This small but important study affirms the potential of this new extravascular approach to provide pacing and lifesaving defibrillation therapy without the risks that accompany transvenous leads implanted inside the heart and veins.”

In the pilot study, 21 patients underwent the EV ICD implant procedure at four sites in New Zealand and Australia. Patients were evaluated at implant, two weeks, four to six weeks, and three months after device implant, and continue to be followed. Study investigators characterized the safety of the system and implant procedure, defibrillation effectiveness, and sensing and pacing:

- At the time of implant, defibrillation testing was completed on 19 patients. The system successfully terminated induced ventricular arrhythmias in 17 patients (89.5 percent), which is consistent with prior clinical studies of existing ICDs.1,2
- Pacing capture was achieved in more than 95 percent of study patients.
- One patient experienced ventricular tachycardia outside the hospital setting, which was successfully detected and treated by the EV ICD system.

“The successful pilot study revealed valuable insights to inform our EV ICD clinical program, and we are eager to incorporate the learnings from this study into a pivotal trial,” said Rob Kowal, M.D., Ph.D., vice president and chief medical officer of the Cardiac Rhythm and Heart Failure division at Medtronic. “Medtronic appreciates the contributions of the investigators and patients, and we are proud to lead the way in ICD innovation for patients who need protection from life-threatening heart rhythms.”

The Medtronic EV ICD system is intended to provide the benefits of traditional, transvenous ICDs including lifesaving defibrillation therapy; anti-tachycardia pacing to terminate arrhythmias; post-shock pacing to protect from sudden cardiac death; and temporary, back-up, bradycardia pacing to address abnormally slow heart rates. It is the same size (33 cc) and shape, and is expected to have similar longevity as traditional ICDs, but without any leads (thin wires that deliver therapy) in the veins or heart. The EV ICD device is implanted in the left mid-axillary region below the left armpit, and the 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, including the ASD3 (Acute Sensing and Defibrillation), SPACE4 (Substernal Pacing Acute Clinical Evaluation), and ASD25 studies. The current EV ICD pilot study continues to generate long-term data on this first-in-human experience.

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 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.

-end-

1 Blatt JA, Poole JE, Johnson GW, et al. No benefit from defibrillation threshold testing in the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial). J Am Coll Cardiol. 2008 Aug 12;52(7):551-6.

2 Neuzner J, Hohnloser SH, Kutyifa V, et al. Effectiveness of single- vs. dual-coil implantable defibrillator leads: An observational analysis from the SIMPLE study. J Cardiovasc Electrophysiol. 2019 Apr 4. doi: 10.1111/jce.13943.

3 Chan JYS, Lelakowski J, Murgatroyd FD et al. Novel Extravascular Defibrillation Configuration With a Coil in the Substernal Space: The ASD Clinical Study. J Am Coll Cardiol EP 2017;3:905-10. https://doi.org/10.1016/j.jacep.2016.12.026

4 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

5 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, 201

---

https://news.medtronic.com/2019-05-11-Medtronic-Reveals-Results-of-First-In-Human-Study-for-Investigational-Extravascular-ICD-System