Medtronic Evera MRI ICD Clinical Study Meets Safety and Efficacy Endpoints

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Late-Breaking Session at Heart Rhythm 2015 Features World's First Randomized Study of an MRI-Conditional Implantable Cardioverter Defibrillator Undergoing Full-Body MRI Scans; Study Simultaneously Published in JACC

DUBLIN and BOSTON - May 14, 2015 - Medtronic plc (NYSE: MDT) today announced clinical trial results for the Medtronic Evera MRI(TM) SureScan® implantable cardioverter defibrillator (ICD) following MRI scans. The study showed that full-body magnetic resonance imaging (MRI) scans do not affect the Evera MRI ICD's ability to detect potentially lethal heart rhythms and deliver life-saving therapy. Data were presented during a late-breaking clinical trial session at Heart Rhythm 2015, the Heart Rhythm Society's 36th Annual Scientific Sessions and published simultaneously in the *Journal of the American College of Cardiology (JACC*).

The Evera MRI Clinical Trial, a multi-center, prospective, controlled clinical trial, is the first randomized study of an MRI-conditional ICD system that allows for full-body 1.5 Tesla (the field strength of the magnet) MRI scans. The Evera MRI ICD includes hardware and software design changes from previous generation devices that differentiate it from other ICDs and allow it to undergo full-body MRIs. The Evera MRI ICD System received CE (Conformité Européenne) Mark in March 2014. The Evera MRI ICD currently is limited to investigational use in the United States.

Unlike other studies looking at MRI safety of ICDs, this robust study included:

- MRI scans of the chest region, where the device is in close proximity to the MRI fields, as well as full-body scans
- Enrollment of pacing-dependent patients, a high-risk group of patients who have either no underlying native heartbeat or an inadequate rate
- Randomization, to help understand the true differences in the clinical outcomes post-MRI by comparing the results to a control group

Currently, patients with ICDs are contraindicated from receiving MRI scans because of potential interactions between the MRI and device function, and the resulting risks to patients who rely on the life-saving therapies of their ICD. As such, there is a critical unmet need for patients suffering from irregular heart rhythms who require ICDs and who also have conditions that warrant MRI scans, which is the gold standard in soft-tissue imaging. As many as 64 percent of patients with an ICD will need an MRI within 10 years of receiving a device.[1]

"The Evera MRI Clinical trial included a broad range of patients with varying medical conditions and co-morbidities who underwent full-body MRI scans to assess the performance of the Evera MRI ICD," said Michael R. Gold, M.D., Ph.D., chief of cardiology, Michael E Assey Professor of Medicine at the Medical University of South Carolina, and principal investigator in the study. "Our goal was to truly push the limits of the ICD, in ways that other studies have not, to ensure it is able to handle the stresses of MRI scans without impacting its ability to deliver potentially life-saving therapy."

About the Evera MRI Clinical Trial

The study enrolled 275 patients at 42 centers around the world. Patients were randomized 2:1 to either undergo a series of MRI sequences of the cardiac, thoracic, cervical and head regions (MRI group), or a one-hour waiting period without MRI (control group). An additional subset of patients in the MRI group had ventricular fibrillation induced following their MRI in order to characterize arrhythmia sensing, detection and therapy delivery.

The study met the safety endpoint, demonstrating 100 percent freedom from MRI-related complications ($p<0.0001$) in the MRI group. The study also met both primary efficacy endpoints. The percentage of MRI and control patients who experienced changes in the electrical performance of their ICD system from pre-MRI/waiting period to one month later

was similar:

- No patients who underwent an MRI experienced a significant increase in the pacing capture threshold (PCT), the amount of energy needed to stimulate the heart. These results were comparable to those in the control group who did not undergo an MRI. (100 percent of MRI patients versus 98.2 percent of non-MRI patients experienced a <=0.5 V increase in ventricular pacing capture threshold, non-inferiority p<0.0001.)
- 99.3 percent of MRI patients and 98.8 percent of control patients experienced either an increase or a <=50 percent decrease in R-wave amplitude, non-inferiority p=0.0001
- The MRI scan did not have any impact on the Evera MRI device's sensing, detection or therapy delivery in patients that experienced ventricular tachycardia / ventricular fibrillation (an abnormally fast or quivering heart rhythm) post-MRI. (34 cases of VT/VF in 24 patients, of which 20 were induced and 14 were spontaneous)

"Access to MRI scans is vital to ICD patients," said Marshall Stanton, M.D., vice president and general manager, Tachycardia business, which is part of the Cardiac and Vascular Group at Medtronic. "Medtronic has long been the leader in developing implantable devices that are approved for use in an MRI environment, and we look forward to being able to provide an MR-conditional ICD to patients."

The Evera MRI ICD is built off of the Evera family of ICDs and includes the following key features and benefits:

- A contoured shape with thin, smooth edges that better fits inside the body, increasing patient comfort by reducing skin pressure by 30 percent[2]
- Industry-leading battery longevity (up to 11 years) compared to previous devices[3-10]
- Pairing with Sprint Quattro® Secure ICD leads, which have 10 years of excellent performance with active monitoring[11] and are the most prescribed ICD leads ever
- SmartShock(TM) 2.0, an exclusive shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms[12]
- OptiVol® 2.0 Fluid Status Monitoring and diagnostics, which is designed to identify patients at risk of worsening heart failure and atrial fibrillation

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 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 the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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