Medtronic News

Medtronic Announces First U.S. Implant of Implantable Cardioverter-Defibrillator System Designed to Allow Full-Body MRI Scans

First Patient Enrolled in U.S. Pivotal Clinical Trial to Evaluate the Evera MRI(TM) ICD System

MINNEAPOLIS - April 22, 2014 -Medtronic today announced the first U.S. implant of the Evera MRI(TM) SureScan® implantable cardioverter-defibrillator (ICD) System, following U.S. Food and Drug Administration (FDA) approval for its Investigational Device Exemption (IDE) application and pivotal clinical trial protocol. Evera MRI is the first ICD system to be evaluated in the U.S. that allows for magnetic resonance imaging (MRI) scans positioned on any region of the body. The first device was successfully implanted at Marquette General Hospital in Marquette, Mich., by Mark Cowan, M.D., as part of the Medtronic randomized, global pivotal clinical trial that will enroll up to 275 patients at approximately 45 centers. The Evera MRI ICD System is currently available only for investigational use in the United States.

It is estimated that that as many as 63 percent of ICD patients will need an MRI within 10 years of receiving a device.[1] Because no ICD system has yet been approved for MR-Conditional use in the U.S., patients with devices have been contraindicated from receiving MRI scans; this is because of the potential interactions between the MRI, ICD function and patient safety.

"ICD patients in the U.S. are frequently denied access to MRI, and results from this clinical trial may give us the evidence needed to make MRI standard," said Michael R. Gold, M.D., Ph.D., Michael E. Assay professor of medicine and director of cardiology at the Medical University of South Carolina, and principal investigator in the study. "We are optimistic about the possibilities that may be ahead for ICD patients, many of whom will need MRI scans during their lifetimes. Adding an ICD that would allow patients to have full-body access to MRI would be a significant breakthrough for this patient population."

Evera MRI is designed to better fit inside the body, with a contoured shape and thin, smooth edges that increase patient comfort by reducing skin pressure by 30 percent.[2] The Evera MRI is designed to maintain the same industry-leading battery longevity (up to 11 years) compared to previous devices.[3],[4],[5],[6],[7],[8],[9],[10] In addition, patients in the study implanted with Evera MRI will receive the Sprint Quattro® Secure family of ICD leads, which has 10 years of proven performance with active monitoring[11] and is designed to be safe in an MRI environment.[12]

Evera MRI includes SmartShock(TM) 2.0 - an exclusive shock reduction algorithm that is designed to enable the device to better differentiate between dangerous and harmless heart rhythms. While the majority of shocks delivered are necessary to treat potentially fatal arrhythmias, studies estimate that approximately 20 percent of patients with implantable defibrillators may experience inappropriate shocks in response to a benign arrhythmia or electrical noise sensed by the device.[13] SmartShock technology has shown to help eliminate these inappropriate shocks, and delivers a 98-percent inappropriate shock free rate at one year.[14],[15] Also included in the Evera MRI is OptiVol® 2.0 Fluid Status Monitoring and complete diagnostics, which is designed to identify patients at risk of worsening heart failure and atrial fibrillation.

"Our goal with the Evera MRI system is to give patients the most unrestricted access to MRI scans, and ultimately allow them to get the diagnostic answers they need," said Marshall Stanton, M.D., vice president and general manager of the tachycardia business at Medtronic. "Medtronic has been a leader in developing implantable devices that are safe for the MRI environment, and we believe ICDs will be no exception in the near future."

The Evera MRI system is the latest addition to a growing number of Medtronic devices which are designed for MRI access including the Medtronic SureScan® pacing systems, neurostimulation systems for the management of chronic pain and the SynchroMed® II programmable drug infusion system.

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.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, 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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[10] Evera XT DR/VR Manual.

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[14] E.J. Schloss et al. Painfree sst trial primary results low shock rates in patients with dual and triple chamber icd's using novel detection algorithms late breaking clinical
trial session - May 10, 2013 at HRS 2013

[15] Meijer et al PainFree SmartShock technology: Trial primary results: Inappropriate shock rates in patients with single chamber ICD's using a novel suite of detection
algorithms. Late Breaking Clinical Trial Session - June 25, 2013 at Europace 2013

Contacts:
Joey Lomicky
Public Relations
+1-763-526-2494

Jeff Warren
Investor Relations
+1-763-505-2696
