Medtronic News

Medtronic Receives FDA Approval for Advisa DR MRI(TM) SureScan(R) Pacing System Clinical Trial

Investigational Second-Generation Device Reinforces Medtronic's Commitment to Innovative Implantable Cardiac Devices Designed for Use in MRI Environment

MINNEAPOLIS, Aug 01, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval for its Investigational Device Exemption (IDE) application and pivotal clinical trial protocol to begin evaluating Advisa DR MRI(TM) SureScan(R) pacing system. FDA approval of the Advisa MRI System Study protocol enables Medtronic to become the first company to conduct a randomized, controlled clinical trial of a second generation pacing system designed for use in the MRI environment under specific scanning conditions in the U.S. The Advisa DR MRI SureScan pacing system is not approved by the FDA for U.S. commercial distribution.

"This clinical trial is an important milestone toward providing another innovative pacing system option for patients who may need access to the potentially life-saving benefits of MRI technology during the lifetime of their device," said Edward J. Schloss, M.D., medical director of electrophysiology at The Christ Hospital in Cincinnati, OH.

Dr. Schloss implanted the first patient in the U.S. with the investigational Advisa MRI System as part of the clinical trial through The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital in Cincinnati.

The Advisa MRI study is a prospective, randomized controlled, non-blinded, multi-center worldwide investigational study to confirm safety and effectiveness of the pacing system in the clinical MRI environment when subjects receive MRI scans under specified conditions, as well as provide data on MRI image quality in the presence of pacing system. In the U.S., the Medtronic Advisa MRI System featuring the SureScan technology is comprised of the Advisa MRI IPG Model A2DR01 and the CapSureFix MRI(TM) active fixation Model 5086MRI lead.

Until FDA approval of Medtronic's first-generation Revo MRI(TM) SureScan(R) pacing system in February 2011, MRI procedures had been contraindicated for patients with implanted pacemakers due to the potential for serious adverse events.i,ii,iii,iv MRI is the standard of care in soft tissue imaging, providing information not seen with X-ray, ultrasound, or CT scan, and critical for early detection, diagnosis and treatment. It is estimated that 50 - 75 percent of patients with an implantable cardiac device will need an MRI scan over the lifetime of their device.

"The FDA approval of the Advisa MRI System Study protocol brings us one step closer to providing patients with another pacemaker option designed for safe use in the MRI environment," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "This clinical trial further demonstrates Medtronic's commitment to leading the industry with clinically proven innovative technologies that enable physicians to help sustain health and extend life."

About Advisa DR MRI(TM) SureScan(R)
Advisa MRI, Medtronic's second-generation pacing system in a portfolio of pacing systems designed, tested, and approved for use as labeled with MRI machines has been available in Europe since 2010. Patients with Advisa MRI in approved countries have access to full body scans, without positioning limitations in the MRI scanner.

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.

i Faris OP, Shein M. Food and Drug Administration perspective: Magnetic resonance imaging of pacemaker and implantable cardioverter-defibrillator patients. Circulation 2006;114:1232-1233.
ii Roguin A, Schwitter J, Vahlhaus C, et al. Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices. Europace 2008;10:336-346.
iii Levine GN, Gomes AS, Arai AE, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention: endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007;116:2878-2891.
iv Kalin R and Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE 2005;28:326-328.

SOURCE: Medtronic, Inc.

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