Medtronic News

Medtronic Achieves Enrollment Milestone in 'CURE-AF'

Clinical Trial of Surgical Tissue Ablation Includes Two U.S. IDE Studies

MINNEAPOLIS, May 03, 2010 (BUSINESS WIRE) --Medtronic, Inc. (NYSE: MDT), today announced completion of patient enrollment in the first of two studies in the company's CURE-AF (Concomitant Utilization of Radiofrequency Energy for Atrial Fibrillation) clinical trial.

The trial consists of two U.S. investigational device exemption (IDE) studies evaluating the safety and effectiveness of the Medtronic Cardioblate(R) Surgical Ablation System as a concomitant treatment for permanent and persistent atrial fibrillation (AF). AF is the most common irregular heart rhythm and contributes to an increased risk of stroke and heart disease.

The Cardioblate System (BP2, LP, Pen, XL Pen, Generator) is currently cleared by the U.S. Food and Drug Administration (FDA) under a 510(K) for the ablation of cardiac tissue. It is not approved by the FDA for the treatment of AF, and the FDA has not yet determined that use of the Cardioblate system for treatment of AF is safe or effective.

CURE-AF will enroll a total of 150 patients at 15 leading U.S. medical centers. Enrollment in the study of 75 patients with permanent AF is now completed, and enrollment in the study of 75 patients with persistent AF is expected to be completed in the next several months.

"Despite the frequency with which atrial fibrillation is confronted by cardiologists and cardiac surgeons, and the frequency of procedures performed to treat the condition, there is little evidence based on rigorous clinical studies to support one approach or another," said Dr. Thoralf Sundt, a cardiothoracic surgeon at the Mayo Clinic in Rochester, Minn., and a CURE-AF primary investigator.

CURE-AF is investigating surgical tissue ablation with the Cardioblate system as a treatment for AF when conducted in conjunction with another open-heart operation, such as surgical valve repair or coronary artery bypass grafting (CABG). During the ablation procedure, surgeons use irrigated radiofrequency energy from the Cardioblate system to create a pattern of lesions on the heart muscle. These lesions are created to block the irregular electrical signals of the heart that cause AF.

"Medtronic pioneered surgical tissue ablation therapy nearly a decade ago," said cardiac surgeon Dr. John Liddicoat, vice president and general manager of the Structural Heart division, part of the CardioVascular business, at Medtronic. "We view CURE-AF as part of an ongoing robust clinical program designed to help support the management of patients with AF."

Following analysis of six months of follow-up data in the permanent AF study and nine-month data in the persistent AF study, Medtronic anticipates submitting applications to the FDA in 2011 for approval of the Cardioblate system for two separate indications: permanent AF and persistent AF.

Atrial fibrillation is a chaotic and uncoordinated contraction of the upper chambers (atria) of the heart. According to the protocol for CURE-AF, permanent AF is characterized as AF in which cardioversion has failed or has not been attempted as defined by the ACC/AHA/ESC Guidelines. Persistent AF is characterized as episodes of non-self-terminating AF that last more than seven days or less than seven days but necessitating pharmacologic or electrical cardioversion.

The primary endpoint for CURE-AF is clinically significant freedom from AF over a 24-hour period in patients off anti-arrhythmic drugs - assessed at six months for the study of permanent AF and at nine months for the study of persistent AF. The safety endpoint for both studies is a composite of acute major adverse event (MAE) rate that is equal to or better than published results using other similar procedures. MAEs - assessed within 30 days post-procedure or hospital discharge, whichever is

longer - include mediastinitis, death, myocardial infarction, stroke, transient ischemic attacks (TIA), pulmonary embolism, peripheral arterial embolism and esophageal injury.

Medtronic CardioVascular is committed to advancing the treatment of coronary, peripheral, aortic and structural heart disease through collaboration with leading clinicians, researchers and scientists worldwide.

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.

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