Medtronic News

New Clinical Trial Will Use Continuous Cardiac Monitoring to Evaluate Atrial Fibrillation in High-Risk Patients

Medtronic Announces First Patient Implant in REVEAL AF Clinical Trial

MINNEAPOLIS - January 16, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the first patient implant for the REVEAL AF (Incidence of AF in High Risk Patients) Clinical Trial, which through continuous cardiac monitoring will evaluate the incidence of atrial fibrillation among patients suspected to be at a high-risk for the disease, and will identify key patient predictors for detection of AF.

Using the Reveal® Insertable Cardiac Monitor (ICM) - a thin device implanted just beneath the skin that continuously records heart activity - the trial will assess how often patients experience atrial fibrillation that lasts six minutes or more, a key measure in determining the incidence of AF in the trial. The trial also will evaluate how physicians manage these patients once atrial fibrillation has been diagnosed, and will identify how the disease can be detected in patients earlier in the continuum of care.

"As a cardiologist I am quite concerned about the risks and complications of atrial arrhythmias, especially thromboembolic complications of atrial fibrillation," said Dr. Eugene Parent, attending cardiologist and director of echocardiography at the Bradenton Cardiology Center and Manatee Memorial Hospital in Bradenton, Fla. "Frequently these rhythm changes are difficult to detect. The Reveal AF study will use the Reveal ICM to detect undiagnosed atrial fibrillation in patients at high risk for thromboembolic complications and allow more effective and prompt treatment of these patients."

In the study, 400 patients from approximately 60 centers in the United States and Europe will be implanted with a Reveal ICM. The Reveal device will transmit information from the patient's heart via Medtronic's CareLink® network, thereby allowing physicians to review patient data remotely. Each patient will be followed for a minimum of 18 months to monitor for atrial fibrillation and have in-office visits every 6 months.

"Atrial fibrillation is the most common arrhythmia, and with a five-fold increase in the risk of stroke, the condition carries significant burdens for patients, as well as on the healthcare system," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Through this study, Medtronic intends to show the clinical value of ICMs in detecting atrial fibrillation so that early-stage therapeutic decisions can be made to improve each patient's quality of life."

Atrial Fibrillation is the most common heart arrhythmia affecting more than 3 million Americans and 7 million people worldwide.[1] The disorder can be difficult to diagnose, as it can occur infrequently and patients may not experience symptoms during an episode. Reveal's around-the-clock monitoring, in contrast with intermittent, external monitoring, can result in earlier and more reliable diagnosis, which can lead to faster treatment. [2]

About the Reveal® XT Insertable Cardiac Monitor

Placed just under the skin of the chest area in a short outpatient procedure, the Reveal XT device provides up to three years of continuous heart rhythm monitoring. Reveal XT captures and stores an electrocardiogram (ECG) automatically, according to physician-programmed settings. Later, a physician analyzes the stored information which can be transmitted remotely via the Medtronic CareLink® Network, or viewed during an in-office patient visit. Clinical data available to the physician includes views of individually stored ECG episodes, or longer-term trended diagnostic data via Reveal XT's Cardiac Compass® Report, including daily atrial fibrillation burden, patient activity and average day and night heart rates.

In collaboration with leading clinicians, researchers and scientists, 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 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.

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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[1] Millennium Research Report; "Global Markets For Atrial Fibrillation Treatment Devices 2008," March 2008; 1.

[2] Paul D. Ziegler, MS, Jodi L. Koehler, MS, Rahul Mehra, PhD. Comparison of continuous versus intermittent monitoring of atrial arrhythmias. Heart Rhythm. December 2006.

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