Medtronic News

New Study Shows Medtronic Insertable Cardiac Monitors Detect High Rate of Atrial Fibrillation in Previously Undiagnosed High-Risk Patients

Results from the REVEAL AF Study Show That AF Would Have Gone Undetected in the Majority of Patients at High-Risk for AF and Stroke If Cardiac Monitoring Was Limited to 30 Days

DUBLIN and CHICAGO - May 12, 2017 - Medtronic plc (NYSE: MDT) today announced results from a new clinical study showing Medtronic Insertable Cardiac Monitors (ICM) detected a high incidence of atrial fibrillation (AF) in patients previously undiagnosed but suspected to be at high-risk for AF and stroke. These data from the REVEAL AF (Incidence of AF in High Risk Patients) study were presented today during a late-breaking session at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions.

The study found that at 18 months, continuous monitoring with either the Reveal® XT ICM or the Reveal LINQ(TM) ICM resulted in an AF detection rate of 29.3 percent among previously undiagnosed high-risk patients (based on clinical risk factors). The data showed continuous monitoring with an ICM detected AF beyond 18 months with a detection rate of 40 percent at 30 months. Additionally, 6.2 percent of patients were diagnosed with AF at 30 days, indicating that more than three-quarters of high risk patients with AF would have gone undetected with only 30 days of cardiac monitoring. The median time from device insertion to the first AF episode was 123 days, which is outside the range of conventional external monitoring.

The Reveal AF study also evaluated how physicians managed patients when AF was found. At least one clinical action was taken in 75.7 percent of patients who were diagnosed with AF (at 18 months). More than half (56.3 percent) of patients diagnosed with AF were prescribed oral anticoagulation by their physicians, which has been shown to significantly reduce stroke risk. This suggests that the information provided by the Reveal ICM was clinically meaningful.

"Detection of AF utilizing minimally invasive insertable cardiac monitors in a high-risk population combined with appropriate AF treatment could prevent many initial strokes," said James Reiffel, M.D., principal investigator of the REVEAL AF Study and professor emeritus of medicine, Department of Medicine, Division of Cardiology at the Columbia Presbyterian Medical Center in New York City. "Findings from the REVEAL AF study show that the rate of AF in patients at high-risk for AF and thus stroke but with no prior history of AF is significant, raising important public health implications on early screening and prevention of stroke in this demographic group."

AF is a common cardiac condition impacting millions worldwide in which the heart beats irregularly or rapidly.1 Patients with AF are five times more likely to have a stroke2 due to small blood clots that may form in the heart and subsequently travel to the brain. Failure to recognize and treat AF can lead to strokes, however, because AF often has no symptoms and may occur infrequently, it may not be detected by conventional cardiac monitoring techniques such as in-hospital monitoring, electrocardiography or traditional ambulatory cardiac monitors such as a Holter.3-6 Unlike conventional monitoring methods, the Reveal LINQ ICM with TruRhythm(TM) Detection automatically and continuously detect and record abnormal heart rhythms for up to three years.

"AF is often undetected with conventional methods and only first diagnosed after the occurrence of a serious complication such as stroke which can result in significant impact to quality of life and even death," said Robert Kowal, M.D., Ph.D., vice president and medical director of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "The REVEAL AF study provides important information to influence how physicians monitor high-risk patients to screen and treat AF, potentially preventing stroke from occurring."

REVEAL AF was a prospective, single-arm, multi-center study that sought to understand the incidence of adjudicated AF that

lasted six minutes or more in high-risk patients who were previously undiagnosed with AF. The primary endpoint of the REVEAL AF study was AF detection rate at 18 months. A total of 385 patients received a Reveal XT ICM or a Reveal ICM and met the primary endpoint cohort definition. Patients were followed for a minimum of 18 months to monitor for AF, or up to a maximum of 30 months.

One-third the size of an AAA battery (~1 cc), the Reveal LINQ ICM is inserted using a minimally invasive procedure and its presence is often nearly undetectable to the naked eye once the incision has healed. The device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink® network and is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed. Earlier this year, Medtronic received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Reveal LINQ ICM with TruRhythm Detection which features improved accuracy to better identify abnormal heartbeats.

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 of the highest quality 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 among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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Contacts:

Ryan Mathre

Public Relations

+1-651-335-2338

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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