Medtronic News

Medtronic Receives CE Mark for Attain Stability(TM) Quad MRI SureScan(TM) Active-Fixation Heart Lead

Clinical Trial Also Underway in U.S., Canada and Other Geographies

DUBLIN - August 21, 2017 - Medtronic plc (NYSE: MDT) announced it has received CE (*Conformité Européene*) Mark for the Attain Stability(TM) Quad MRI SureScan(TM) left heart lead. Paired with Medtronic quadripolar cardiac resynchronization therapy-defibrillators (CRT-D) and -pacemakers (CRT-P), the Attain Stability Quad lead features novel, active-fixation technology that is designed for precise lead placement and stability. *In the United States, the Attain Stability Quad lead is under evaluation in a clinical trial and is not approved for sale.*

The company has undertaken a limited European launch, and first commercial implants recently were performed at Haukeland University Hospital, Bergen, Norway.

"This new lead provides another option for left ventricular lead placement that can meet the needs of patients with various anatomies," said Prof. Svein Faerestrand, Haukeland University Hospital. "We now have the ability to place the lead where we want within the vessel."

CRT is a treatment for heart failure in which an implantable device sends low levels of energy through thin wires, called leads, to stimulate the heart muscle and improve the heart's pumping efficiency. The Attain Stability Quad lead, which is approved in CE Marked geographies for 3 Tesla (T) and 1.5T magnetic resonance imaging (MRI) scans, features a side-helix designed to be fixated precisely in veins of various sizes. Four electrodes (quadripolar technology) allow physicians flexibility in finding the optimal location for stimulating the heart.

Medtronic also has initiated a global, prospective, non-randomized, multicenter clinical study to evaluate the safety and effectiveness of the lead in heart failure patients. The study will enroll up to 471 patients across 56 sites in the United States, Canada, Europe, Hong Kong and Malaysia. The primary efficacy endpoint will evaluate the number of patients that have appropriate pacing capture thresholds in at least two programming configurations, and the primary safety endpoint is lead-related complication-free rate at six months. Co-principal investigators are Kevin Jackson, M.D., heart rhythm specialist at Duke Raleigh Hospital, and assistant professor of medicine at Duke University, and George Crossley, III, M.D., associate professor of medicine and electrophysiologist at Vanderbilt Heart and Vascular Institute. Toshimasa Okabe, M.D., recently performed the first implant in the clinical trial at Ross Heart Hospital of The Ohio State University Wexner Medical Center.

"LV lead positioning and stability remain a challenge for physicians," said Dr. Jackson. "Acute and chronic lead dislodgement are still concerns. This lead's active-fixation mechanism gives us another option to get to the desired pacing location, and stay there."

"We look forward to obtaining results from the Attain Stability Quad clinical study to support approvals in new geographies and reach more patients," said Kweli P. Thompson, M.D., M.P.H., vice president and general manager of the Cardiac Resynchronization Therapy business, part of the Cardiac Rhythm and Heart Failure division at Medtronic. "Medtronic is committed to helping physicians treat patients with heart failure by pioneering advancements in CRT, and creating therapies that provide more personalized treatment."

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 91,000 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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