Medtronic News

Medtronic Starts International Study of CoreValve(R) Transcatheter Aortic Valve System

Post-Market Evaluation of Breakthrough Medical Device Begins Enrolling Patients; First Implants Occur in Germany
MINNEAPOLIS, Mar 12, 2010 (BUSINESS WIRE) -- Moving to expand the evidence base for the future of structural heart disease therapy,Medtronic, Inc. (NYSE: MDT), today announced the start of the first of several new initiatives in a robust international clinical program for its CoreValve transcatheter aortic valve system, a minimally-invasive alternative to open-heart surgery for aortic valve replacement.

The CoreValve Advance clinical study began enrolling patients last week, with the first two implants occurring in Germany. CoreValve Advance is a prospective, observational international post-market study to evaluate clinical outcomes of patients with severe aortic stenosis who are treated with the CoreValve system in standard clinical practice. The CoreValve system received CE (Conformité Européenne) Mark in March 2007. It is not yet available in the United States for commercial sale or clinical use.

"The CoreValve Advance study is Medtronic's first major clinical evaluation of the CoreValve system since we acquired it in April 2009," said cardiac surgeon Dr. John Liddicoat, vice president and general manager of the Structural Heart division, part of the CardioVascular business, at Medtronic. "The study demonstrates our commitment to leverage Medtronic's global clinical research expertise to strengthen the body of evidence for this breakthrough medical device. "It is one of several CoreValve studies planned to begin this year worldwide as part of a rigorous, long-term clinical program to be further enhanced by innovative system advancements."

Approximately 1,000 patients with severe aortic stenosis will be enrolled in CoreValve Advance at up to 90 clinical trial sites in countries where the CoreValve system is commercially available. Most of the trial sites will be in Europe, where the CoreValve system is used in approximately 75 percent of transcatheter aortic valve replacements involving percutaneous femoral access.

The principal and co-principal investigators of CoreValve Advance are Prof. Axel Linke, Universität Leipzig Herzzentrum, and Prof. Robert Bauernschmitt, Deutches Herzzentrum München, both in Germany. The first study procedures were performed by Prof. Horst Sievert, CardioVascular Center Frankfurt, also in Germany.

"We have been very pleased with past clinical results using the CoreValve system, and we anticipate great scientific value for future patients by participating in the CoreValve Advance study," said Prof. Sievert. "The resulting data will provide important information to physicians and regulatory officials worldwide related to broad-scale safety and device performance for patients with severe aortic stenosis who often are at high risk for open-heart surgery."

Study patients will be followed for at least five years following implantation of CoreValve. The primary endpoint is Major Adverse Cardiac & Cerebrovascular Events (MACCE) at 30 days following the procedure, with MACCE defined as a composite of: all-cause mortality; myocardial infarction; emergent cardiac surgery or percutaneous re-intervention; and stroke. The study also includes 19 secondary endpoints and data collection related to the health economic impact of CoreValve on patient quality of life and therapy cost-effectiveness.

The CoreValve system is designed to enable replacement of a diseased aortic valve without open-heart surgery or surgical removal of the native valve. Typically delivered through the femoral artery, it has been implanted in more than 7,500 patients worldwide and is now available in 29 countries outside the United States.

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

ABOUT MEDTRONIC

Medtronic, Inc. (http://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.

NOTE: CoreValve is a registered trademark of Medtronic CV Luxembourgh S.a.r.l.

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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