Medtronic Begins Global Clinical Trial Evaluating CoreValve® System Implantation in Intermediate-Risk Patients

The Associated Press

MINNEAPOLIS - July 18, 2012 - Medtronic, Inc. (NYSE: MDT) today announced the first patient enrollment in a global, multicenter, randomized clinical trial comparing the Medtronic CoreValve® System with surgical aortic valve replacement in patients with severe aortic stenosis who are at intermediate risk to undergo open-heart surgery. The trial, called Medtronic CoreValve Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial, will evaluate the potential for the minimally-invasive CoreValve System to be considered for less-sick patients who typically are treated with open-heart surgical aortic valve replacement (SAVR) today.

The first patient procedures in the SURTAVI trial occurred at Rigshospitalet Copenhagen University Hospital in Copenhagen, Denmark, and were performed by Lars Søndergaard, M.D., interventional cardiologist, and Daniel Steinbrüchel, M.D., DMSc, cardiaothoracic surgeon.

"Transcatheter aortic valve replacement is a transformational, potentially lifesaving technology that typically is used to treat inoperable patients or patients for whom surgery carries high risks," said Patrick Serruys, M.D., Ph.D., professor of medicine and head of the Department of Interventional Cardiology at Erasmus Medical Center in Rotterdam, The Netherlands, and chairman of the SURTAVI trial. "The SURTAVI trial will offer guidance on how to best treat intermediate risk patients and may substantiate the CoreValve System as an attractive alternative treatment for these patients."

The Trial will be the largest global, randomized, controlled trial on transcatheter aortic valve implantation (TAVI) and will nominally evaluate approximately 2,500 patients at up to 75 clinical sites with experienced heart teams that include interventional cardiologists and cardiac surgeons. The trial will evaluate whether the CoreValve System is non-inferior to surgical valve replacement, based on the composite primary endpoint of all-cause mortality and major stroke at 24 months. Medtronic is working with the U.S. Food and Drug Administration to include U.S. patients in the trial.

Patients considered for the trial include those with severe, symptomaticaortic stenosis who are classified as intermediate surgical risk, as defined by a Society of Thoracic Surgeons' (STS) mortality risk of ≥4 percent and ≤ 10 percent. Patients will be randomized on a 1:1 basis to either TAVI with CoreValve or to surgery. CoreValve implantation can be performed by transfemoral, subclavian or

direct aortic access, depending on the needs of the patient. All patients will be followed through five years.

"We are pleased to begin this important trial that may demonstrate the benefits of the CoreValve System in a broader population of patients with severe aortic stenosis," said A. Pieter Kappetein, M.D., Ph.D., principal investigator of the SURTAVI trial and professor of cardiothoracic surgery at Erasmus Medical Center in Rotterdam, The Netherlands. "This study represents a significant opportunity to bring a new therapy to physicians and a large percentage of patients, both of whom are looking for a less invasive option to treat aortic stenosis."

The Medtronic CoreValve System received CE (Conformite Europeenne) Mark in 2007. The CoreValve System is available in three sizes (26mm, 29mm and 31mm), and is the only transcatheter aortic valve implantation system approved for implantation via the direct aortic approach and the subclavian approach. The CoreValve System is currently limited to investigational use in the United States.

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.

About Medtronic Medtronic, Inc. (www.medtronic.com [1]), 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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