Major TAVI Trial Under Way

Medtronic, Inc. today announced the first treatment of a U.S. patient in its 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 Medtronic CoreValve Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial is evaluating the minimally-invasive CoreValve System in less-sick patients who typically are treated with open-heart surgical aortic valve replacement today.

"The SURTAVI trial will provide guidance on how to best address intermediate risk patients, who along with their physicians are looking for less invasive options for treating aortic stenosis," said Michael Reardon, M.D., co-principal investigator of the SURTAVI Trial and Weill Cornell Professor of Cardiothoracic Surgery at The Methodist DeBakey Heart and Vascular Center in Houston. "The Trial may demonstrate that the CoreValve System is beneficial to this broader population of patients who are looking for alternative treatments."

The SURTAVI Trial will be the largest global, randomized, controlled trial on transcatheter aortic valve implantation (TAVI) to date and will include approximately 2,500 patients. These patients will be evaluated and treated by experienced heart teams that include interventional cardiologists and cardiac surgeons. The first patient procedure occurred at Pinnacle Health System in Harrisburg, PA by the heart team of Brijeshwar Maini, M.D., and Mubashir Mumtaz, M.D.

The trial will evaluate whether the CoreValve System is non-inferior to surgical aortic valve replacement, based on the composite primary endpoint of all-cause mortality and disabling stroke at 24 months.

Patients considered for the trial include those with severe, symptomatic aortic stenosis who are classified as intermediate surgical risk, as defined by The Society of Thoracic Surgeons' (STS) as a predicted mortality risk of >= 4 percent and <= 10 percent. Patients will be randomized on a 1:1 basis to either CoreValve implantation or to surgical aortic valve replacement. 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.

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.

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