Medtronic News

Medtronic CoreValve® System Results Superior to Open-Heart Surgery at One Year in U.S. Pivotal Trial

CoreValve High Risk Study: FDA Determines Expert Panel Not Required
Low Mortality Rate Exceeds Expectations for Primary Endpoint
CoreValve System is First and Only Transcatheter Aortic Valve to Show Results Superior to Surgical Aortic Valve Replacement

MINNEAPOLIS and WASHINGTON - March 29, 2014 - Medtronic, Inc. (NYSE: MDT) today announced that the CoreValve® System showed results superior to surgical aortic valve replacement (SAVR) at one year in the High Risk Study of its CoreValve U.S. Pivotal Trial, which evaluated patients with severe aortic stenosis who are considered high risk for surgery. The data were presented at a late-breaking clinical trial session at the 63rd Annual Scientific Session of the American College of Cardiology (ACC) and simultaneously published in *The New England Journal of Medicine*.

The CoreValve System was approved by the U.S. Food and Drug Administration (FDA) in January 2014 for patients considered extreme risk for surgery; the device is not currently approved in the U.S. for use with patients at high risk.

The head-to-head study met its primary endpoint with a low one year, all-cause mortality rate of only 14.2 percent in patients receiving the CoreValve System, compared to 19.1 percent in patients receiving SAVR at one year (non-inferiority p-value<0.001; superiority p-value=0.04). The CoreValve High Risk Study is the first prospective, randomized study to show any transcatheter aortic valve to be superior to surgery.

"The extremely low mortality rates in both arms of the trial confirm that our heart teams were outstanding, particularly considering they had no prior experience with transcatheter aortic valve therapy, said David H. Adams, M.D., chair of the Department of Cardiothoracic Surgery at the Mount Sinai Hospital, New York City, national co-principal investigator of the CoreValve U. S. Pivotal Trial and presenter of the data at ACC. "Our key finding that TAVR with CoreValve was associated with a significantly higher rate of survival at one year in patients at increased risk has significant and broad implications."

Stroke rates in patients with the CoreValve System were low and not statistically different than in SAVR patients; this finding is especially important because stroke is one of the complications most concerning to physicians and patients because it increases mortality and affects quality of life. As determined by detailed neurological assessments before and after each procedure, major stroke rates in patients who received the CoreValve System were 3.9 percent at 30 days and 5.8 percent at one year, while those same rates for patients with surgery were 3.1 percent (30 days) and 7.0 percent (one year).

Patients also saw significant improvements in their quality of life (QoL). QoL scores improved 19.0 points for CoreValve patients and 3.7 points for surgical patients at 30 days (p=<0.0001); at one year both patient groups improved significantly with CoreValve patients improving 23.2 points and surgical patients improving 21.9 points (as measured by KCCQ 100-point scale, where five points is considered important, and 20 points is considered a very large improvement).

"The results of the High Risk study confirm our findings in the Extreme Risk Study, namely that careful pre-procedural planning with CT-based determination of valve sizing and attention to 'best practice' implantation techniques result in a strong hemodynamic performance of the self-expanding CoreValve with low rates of one

year paravalvular regurgitation and stroke," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center, Boston, and national co-principal investigator of the CoreValve U.S. Pivotal Trial.

While there was no statistical difference between CoreValve System and surgery in MACCE (major adverse cardiovascular or cerebral events) rates at 30 days (p=0.1), at one year the MACCE rate was significantly better for CoreValve patients (p=0.03). The frequency of death or major stroke at one year was also lower with CoreValve (p=0.03). Overall hemodynamic (blood flow) performance in CoreValve patients was better than SAVR across all time points (p=<0.02 at discharge, 30 days and one year). In addition, rates of moderate or severe paravalvular leak (PVL) for TAVR were acceptably low with 7.8 percent at discharge and 6.1 percent at one year. Consistent with the Extreme Risk Study, PVL in most patients improved over time. As with previous studies on self-expanding technology, the permanent pacemaker rate was 19.8 percent at one month and, importantly, for these patients a difference in mortality was not observed.

"The results of the CoreValve High Risk Study effectively demonstrate the value of the heart team approach, with an equal number of cardiac surgeons and interventionalists generating the compelling clinical outcomes," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "We applaud the investigators for their commitment to this rigorously designed study and for its meticulous execution. We also look forward to the potential impact these data will have on improving patient outcomes in real-world clinical practice once the CoreValve System receives FDA approval for patients at increased risk."

To participate in the High Risk study, the 747 patients were estimated to have a predicted risk of operative mortality of 15 percent or higher at 30 days, assessed by two clinical site surgeons and confirmed by at least two surgeons on a National Screening Committee. The average age of patients in the study was 83.2 years old, and the study enrolled a nearly equal number of men and women. In addition to the STS Predicted Risk of Mortality estimate of 7.4, these patients had documented co-morbidities, frailty and disability that placed them at increased risk for surgery. The majority of patients (56 percent) had a Charlson co-morbidity score of 5 or greater (on a scale of 6, where 5 or greater represents severe co-morbidity). Ten percent of patients did not live independently.

The CoreValve System was approved by the U.S. Food and Drug Administration (FDA) in January 2014 for patients considered extreme risk for surgery. Since receiving CE (Conformité Européenne) Mark in 2007, the CoreValve System has been implanted in more than 50,000 patients in more than 60 countries.

Update on FDA Review of CoreValve High Risk Study

Upon reviewing the CoreValve Trial's results for high risk patients, the FDA has determined it has sufficient information to evaluate the safety and efficacy of the Medtronic CoreValve System for this patient group without the need for an external expert panel.

The CoreValve System was designed specifically to overcome the challenges of a broad range of TAVR patients. The device has a small 18Fr profile for all valve sizes, which minimizes trauma at implant, and allows physicians to treat patients with small or calcified vasculature. Its Nitinol frame is designed to prevent unwanted leakage and optimize blood flow. In addition, the CoreValve System is available in the broadest range of sizes available, so patients who have smaller, larger or in-between sizes can be accommodated.

The Company will webcast an Investor Briefing later today, where Medtronic management will review these

clinical results. The live audio webcast of the presentation can be accessed beginning at 11:00 a.m. EDT by clicking on the Investors link on the Medtronic home page at http://www.medtronic.com. Within 24 hours of the webcast, a replay will be available under the Events and Presentations page in the Investors section of the Medtronic website. This event is not part of ACC.14, as planned by its Program Committee, and does not qualify for continuing medical education (CME), continuing nursing education (CNE) or continuing education (CE) credit.

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 that deliver clinical and economic value to healthcare consumers and providers around the world.

ABOUT MEDTRONIC
Medtronic, Inc. (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.

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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