Medtronic CoreValve® System Sustains Superior Survival Benefit Over Open Heart Surgery at Two Years

March 15, 2015 12:45 PM CT

Investigators Conclude that Results Presented as ACC.15 Late-Breaking Clinical Trial Suggest that Self-Expanding TAVR Should be Considered New Standard of Care

DUBLIN and SAN DIEGO - March 15, 2015 - Medtronic plc (NYSE: MDT) today unveiled new, highly anticipated two-year data from the High Risk Study of the CoreValve U.S. Pivotal Trial, which continued to show superior survival benefit at two years for transcatheter aortic valve replacement (TAVR) with the CoreValve® System compared to patients who underwent surgical aortic valve replacement (SAVR). The CoreValve US Pivotal High Risk Study is the first and only head-to-head study to show statistically significant survival differences favoring TAVR in aortic stenosis patients who are considered high risk for surgery.

Presented as a late-breaking clinical trial at the 64th Annual Scientific Session of the American College of Cardiology (ACC.15), the two-year outcomes from the CoreValve High Risk Study found that the rate of all-cause mortality was significantly lower in TAVR patients than in the SAVR patients (22.2 percent vs. 28.6 percent, *p*=0.04), with the absolute difference in all-cause mortality increasing between the two groups from 4.8 percent at one year to 6.5 percent at two years.

"In this trial CoreValve maintains a low and stable stroke rate and the recovery advantages CoreValve demonstrated at one year are maintained at two years. Current ACC/AHA guidelines refer to TAVR as a reasonable alternative to SAVR in high risk patients as judged by the heart team; however, these clinical data suggest a change in these guidelines may be warranted for the self-expanding valve in this patient population," said Michael Reardon, M.D., professor of cardiothoracic surgery at Houston Methodist DeBakey Heart & Vascular Center, and chairman of the patient screening committee of the CoreValve U.S. Pivotal Trial. "Further, I believe that the results of this randomized study suggest that self-expanding transcatheter valve therapy should be considered standard of care and preferred over surgery in this patient population."

Using robust prospective evaluation, the rate of stroke was significantly lower in the TAVR group as compared to the SAVR group at two years (10.9 percent vs 16.6 percent, *p*=0.05), and the major stroke rates were comparable (6.8 percent vs. 9.8 percent; *p*=0.25). The combined endpoint of all-cause mortality or major stroke significantly favored the TAVR group (24.2 percent vs. 32.5 percent, *p*=0.01).

Rates of major adverse cardiovascular and cerebrovascular events (MACCE) at one year were still superior at two years and were statistically lower in the TAVR group than the SAVR group (29.7 percent vs. 38.6 percent, *p*=0.01). While the echocardiographic parameters of effective orifice area and mean aortic-valve gradient remained stable for both groups over the two year period, the TAVR group showed superior hemodynamics (blood flow) compared with the surgical group at all time points during the clinical trial follow-up (*p*=<0.001). Moderate to severe paravalvular regurgitation (PVL) for the TAVR group at two years (6.1 percent) proved consistent with the low one-year rate.

The CoreValve High Risk Study randomized 747 severe aortic stenosis patients at 45 centers in the United States to treatment with either the CoreValve System or open-heart surgery. The 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 percent, these patients had documented co-morbidities, frailty and disability that placed them at increased risk for surgery.

The CoreValve System was approved by the U.S. Food and Drug Administration (FDA) in 2014 for patients at extreme risk and high risk for surgery. Since receiving CE (Conformité Européenne) Mark in 2007, the CoreValve System has been implanted in more than 75,000 patients in more than 60 countries. In addition, the CoreValve System offers the broadest range of sizes available to accommodate more patients.

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 plc (www.medtronic.com), headquartered in Dublin, 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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