Medtronic News

Medtronic CoreValve® System Shows Positive Clinical Outcomes in New Patient Populations

New Data Show Low Mortality and Improved Quality of Life for Patients with Failed Surgical Aortic Valves, End-Stage Renal Disease and Low Gradient Aortic Stenosis

DUBLIN and SAN FRANCISCO - October 13, 2015 - Medtronic plc (NYSE: MDT) today unveiled new clinical data that showed positive clinical outcomes at one year for the CoreValve System in new patient populations with significant co-morbidities. Results from three patient populations evaluated within the CoreValve® U.S. Expanded Use Study were presented at the Transcatheter Cardiovascular Therapeutics (TCT) symposium in San Francisco.

The three populations included patients with a degenerated surgical bioprosthesis, patients with end-stage renal disease, and patients with low gradient aortic stenosis. While transcatheter aortic valve replacement (TAVR) is not approved for the latter two patient populations, in March, the CoreValve System was the first transcatheter heart valve approved in the U.S. for valve-in-valve procedures in both high and extreme risk patients with failed surgical valves.

"It's encouraging to see patients benefitting from the CoreValve System, many of whom have been unable to receive treatment due to these severe comorbidities," 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. "When treated with the CoreValve system, not only do these patients live longer, they are able to achieve and maintain a good quality of life, which is really important for these individuals and their loved ones."

VALVE-IN-VALVE

Contributing to CoreValve's first-of-its-kind approval by the U.S. Food and Drug Administration (FDA) in March 2015 for valve-in-valve procedures, new data on 109 patients with failed surgical valves in the Expanded Use Study showed a low rate of all-cause mortality (13.4 percent) and major stroke (3.1 percent) at one year. These rates included patients with small surgical valve sizes (17mm inner diameter) who had not been previously studied. Importantly, all patients demonstrated a statistically significant improvement in quality of life as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ), with an average improvement of 31.8 at one year ($P < 0.001$) on the 100-point scale. Additionally, 93.6 percent of the initial 109 patients were in NYHA class III and IV at baseline, and in the surviving patients at one year, 73.2 percent were in NYHA Class I.

Patients in the Valve-in-Valve study also experienced a low rate of moderate aortic regurgitation (6.4 percent) with no cases of severe regurgitation (0.0 percent), and benefitted from strong hemodynamic performance with a mean gradient of 16.5mmHg at one year despite placement within small surgical valves.

"In valve-in-valve procedures, the CoreValve system's unique supra-annular design helps maximize blood flow through the aortic valve, which is particularly important when implanting within a surgical valve where the original orifice area is often compromised. TAVR provides physicians with an alternative treatment option for patients facing another open heart surgery," continued Dr. Reardon.

END-STAGE RENAL DISEASE

Another subset from the Expanded Use Study included patients with end-stage renal disease, who also showed a low rate of mortality and stroke. Despite the clinical challenges of treating this patient population, CoreValve exceeded the objective performance goal for all-cause mortality or major stroke set out in the original CoreValve Extreme Risk Study (30.3 percent in this population vs. the objective performance goal of 43 percent in the US Pivotal ER). Additionally, the rate of all-cause mortality among the end-stage renal patients in the Expanded Use Study was lower than that of patients undergoing dialysis in the Transcatheter Valve Therapy (TVT) Registry (30.3 percent vs. 41 percent). End-stage renal patients also showed a

significant improvement in quality of life at one year with an average increase in the KCCQ overall summary score of 27.5 points compared to baseline.

LOW GRADIENT AORTIC STENOSIS

Findings from the low gradient aortic stenosis (LG-AS) patient population within the Expanded Use Study were also comparable to the CoreValve Extreme Risk Study. Patients with LG-AS treated with the self-expanding valve had a low rate of all-cause mortality or major stroke whether or not they had LG-AS with *normal* ejection fraction (26.0 percent for LG-NEF, N=113) or LG-AS with *low* ejection fraction (26.3 percent for LG-LEF, N=46). The KCCQ score confirmed the patients' improvement in quality of life at one year with average improvements of 25.8 (LG-NEF) and 30.5 (LG-LEF), respectively.

The CoreValve System is approved by the FDA for patients at extreme risk and high risk for surgery. Since receiving CE (Conformité Européenne) Mark in 2007, the CoreValve System, and the recently approved CoreValve Evolut R System, has been implanted in more than 80,000 patients in more than 60 countries. To date, the CoreValve system is not FDA approved for patients with end stage renal disease or low gradient aortic stenosis.

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, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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