

Medtronic CoreValve® System Demonstrates Positive Clinical Performance at Two Years in 'Real World' ADVANCE Study

Rigorous Two-Year Analyses Presented at EuroPCR 2014 Affirm Safety, Efficacy and Sustained Valve Performance of Self-Expanding Valve

PARIS and MINNEAPOLIS - May 21, 2014 - Medtronic, Inc. (NYSE: MDT) today revealed new data showing that patients treated with the CoreValve® System experienced positive clinical outcomes in the rigorous "real world" Medtronic CoreValve ADVANCE Study. Presented at EuroPCR 2014, the transcatheter aortic valve implantation (TAVI) study revealed low rates of mortality and stroke, and showed exceptional valve performance through two years.

Two-year follow-up was reported on 96.8 percent of 1,015 patients, all of whom had severe aortic stenosis and were treated with the CoreValve System. Patients experienced low rates of all-cause mortality (25.6 percent), cardiovascular mortality (16.8 percent) and major stroke (2.9 percent) at two years. These findings are consistent with the positive findings previously reported at one-month and one-year.

A majority of patients experienced dramatic improvement in symptoms through two years (87 percent improved to New York Heart Association class I or class II). Overall hemodynamic (blood flow) performance was strong and stable, with mean gradients (resistance) remaining below 10 mmHg, a commonly used threshold of exceptional blood flow, at each follow-up visit out to 2 years (9.8 at discharge, 9.5 at 1 year and 9.4 at 2 years).

"It's impressive to see that these positive clinical outcomes sustain out to two years, affirming the safety and exceptional performance of the CoreValve System," said Axel Linke, M.D., professor of medicine at Universitat Leipzig Herzzentrum in Leipzig, Germany, and principal investigator of the ADVANCE clinical trial. "These contemporary real-world data, combined with results from the rigorous randomized trial in the U.S., are important in understanding how TAVI performs and help physicians determine which options are best for their patients."

The international ADVANCE Study was conducted with experienced TAVI heart teams across 44 centers in 12 countries, with patient receiving CoreValve implants between March 2010 and July 2011. The study calculated clinical endpoints according to Valve Academic Research Consortium (VARC) standardized definitions. All data were independently monitored, all adverse events related to primary endpoints were adjudicated by an independent Clinical Events Committee (CEC) consisting of experienced cardiac surgeons and interventional cardiologists, and all cerebrovascular events (including stroke and other events) were adjudicated by an independent neurologist using neuroimaging and systematic NIH Stroke Scale assessments.

A separate analysis comparing patients 75 years and younger (n=182) with older patients (n=833) in the ADVANCE Study showed that both age groups benefitted from CoreValve treatment, demonstrating similar and low all-cause mortality rates at 30 days, 12 months, and two years (23.6 percent vs. 26.0 percent, p=0.448 at two years). No significant differences were observed between the two age groups for rates of cardiovascular mortality, stroke, myocardial infarction, bleeding, moderate and severe paravalvular leak, or the need for a new permanent pacemaker at either 1 or 2 years. At baseline, patients 75 years and younger had considerably higher rates of comorbidities at baseline compared to older patients.

The CoreValve ADVANCE Study data were presented at EuroPCR 2014 by Prof. Linke, Johan Bosmans, M.D., professor of medicine at University Hospital Antwerp, Belgium, and Ulrich Gerckens, M.D., of Gemeinschaftskrankenhaus in Bonn, Germany.

The CoreValve System was approved by the U.S. Food and Drug Administration in January 2014 for patients considered at extreme risk for surgery; in the U.S., CoreValve System is investigational for other patient groups. Since receiving CE

(Conformité Européenne) Mark in 2007, the CoreValve System has been implanted in more than 60,000 patients in more than 60 countries.

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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