Medtronic News

Medtronic CoreValve ADVANCE Study Demonstrates Low Rates of Mortality and Stroke and Sustained Valve Performance

EuroPCR Presentation of One-Year Data from Robust "Real World" Global Study Demonstrates One of the Lowest Mortality Rates among Similar TAVI Studies

PARIS -- May 21, 2013 -- Committed to generating robust clinical data on its CoreValve System for transcatheter aortic valve implantation (TAVI), Medtronic, Inc. (NYSE: MDT) today unveiled for the first time the complete one-year data from the "real world" Medtronic CoreValve ADVANCE Study. Presented at EuroPCR 2013, the one-year findings from the rigorous study showed low rates of mortality and stroke, along with significant and sustained hemodynamic (blood flow) performance.

Consistent with positive one-month clinical outcomes previously reported, the ADVANCE Study demonstrated a low all-cause mortality rate of 17.9 percent, a cardiovascular mortality rate of 11.7 percent, and a very low and stable overall stroke rate of 4.5 percent (minor: 2.3/major: 2.2) at one year. Patients followed to one year also experienced significant and sustained improvements in hemodynamics due to the implanted CoreValve.

In addition, patients experienced dramatic symptomatic improvements: while at baseline only 20 percent of patients were classified as NYHA (New York Heart Association) class I or class II, clinical symptoms markedly improved with 85 percent of patients in NYHA class I or II at 30 days, and 87 percent of patients in NYHA class I or II at 12 months.

Among the 996 treated patients with severe aortic stenosis and deemed at high-risk for surgical aortic valve replacement (SAVR), one-year follow-up was reported on 806 patients out of 824 patients available at one-year (97.8 percent).

"The compelling clinical results found in ADVANCE at one year are among some of the lowest reported rates of mortality and stroke across similar, large-scale TAVI studies," said Johan Bosmans, M.D., professor of medicine at University Hospital Antwerp, Belgium, and an investigator in the ADVANCE Study. "These positive clinical outcomes, combined with sustained rates of hemodynamic improvements demonstrate that CoreValve sets a high standard in some of the most relevant TAVI endpoints."

One of the largest "real world" (common medical practice) TAVI trials to date, the international ADVANCE Study was conducted with experienced TAVI heart teams across 44 centers in 12 countries. It is one of the most rigorous TAVI clinical studies to date, with clinical endpoints calculated 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.

Since receiving CE (*Conformité Européenne*) Mark in 2007, the CoreValve System has been implanted in more than 40,000 patients in more than 60 countries. The CoreValve System offers the broadest available size range (23mm, 26mm, 29mm and 31mm), deliverable via transfemoral, subclavian and direct aortic access through a low-profile, 18Fr delivery catheter. The CoreValve System is not currently approved for commercial use in the United States and is undergoing clinical trials in the U.S.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the treatment of cardiovascular disease. 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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