Medtronic News

Data Presented at ACC Reinforce Positive Clinical Outcomes for Patients Receiving Medtronic's CoreValve® System

MINNEAPOLIS--(BUSINESS WIRE)--Mar. 24, 2012--Medtronic, Inc. (NYSE: MDT) today announced results from its largest international, prospective, single-arm clinical trial evaluating the Medtronic CoreValve® System in patients with severe aortic stenosis who are at high-risk for surgical aortic valve replacement (SAVR). These data, presented at The American College of Cardiology's (ACC's) 61st Annual Scientific Session & Expo in Chicago, showed that patients in a real-world setting experienced high procedural success combined with positive clinical outcomes. The CoreValve System is currently limited to investigational use in the United States.

Called the Medtronic CoreValve ADVANCE Study, survival rates were high at both 30 days (95.5 percent) and 6 months (87.2 percent), rates that are consistent with previously reported data from national registries in Europe. The procedural success rate was 97.8 percent, and overall complication rates were low with stroke rates of 2.9 percent and MACCE (Major Adverse Cardiac & Cerebrovascular Events) rates of 8.3 percent at 30 days. Patients in the study experienced significant improvement in valve function (mean gradient decreased from 45.6 mmHg at baseline to 9.3 mmHg at 30 days).

The study is one of the largest multicenter transcatheter valve trials to date, with 1,015 patients (mean age of 81 years) consecutively treated at 44 experienced transcatheter aortic valve implantation (TAVI) centers in 12 countries internationally. Clinical endpoints in the trial were calculated according to Valve Academic Research Consortium (VARC) standardized definitions. All data were independently monitored, all adverse events related to the 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.

"The ADVANCE study is a very well conducted and robust clinical trial that provides a contemporary look into the treatment of TAVI patients, and it found that patients with severe aortic stenosis who are at risk for surgery benefit when they are treated with the CoreValve System," said Axel Linke, M.D., professor of medicine at Universitat Leipzig Herzzentrum inLeipzig, Germany and principal investigator of the ADVANCE clinical trial. "The high rate of procedural success, strong hemodynamics and valve performance, combined with positive clinical outcomes validates the existing body of evidence accumulated to date for the CoreValve system."

The Medtronic CoreValve System received CE (Conformite Europeenne) Mark in 2007 for treatment of patients deemed at high or extreme risk for SAVR. Since 2007, it has been implanted in more than 26,000 people in more than 50 countries outside the U.S. The CoreValve System is available in three sizes (26mm, 29mm and 31mm), and is the only transcatheter aortic valve implantation system approved for direct aortic or subclavian access.

"This study adds considerably to the strong body of clinical results that demonstrates the advantages of the CoreValve System in a real-world clinical application," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "ADVANCE is an important piece of Medtronic's full portfolio of clinical studies – all designed to enhance our clinical knowledge about CoreValve therapy, with the goal of providing patients who have severe aortic stenosis with a clinically effective and safe treatment option for treating this disease."

Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery.1

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.

1 *Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?* Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.

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