Medtronic News

Study Shows Medtronic CoreValve(R) System Efficacy and Durability Through Four Years in Longest-Term Industry Data Available

PARIS, Aug 28, 2011 (BUSINESS WIRE) -- New clinical data presented today at the European Society of Cardiology Congress 2011 demonstrate positive long-term performance for the CoreValve(R) transcatheter aortic valve replacement system from Medtronic, Inc. (NYSE: MDT). The study monitored patients through four years - the longest follow-up in a published study of any transcatheter aortic valve implantation (TAVI) system to date - and found the CoreValve System maintained its structural integrity and led to positive clinical outcomes.

The study followed 50 patients (average age of 81 years) with native aortic valve disease who were implanted with the 21F CoreValve system in 2005 and 2006 at seven centers in Europe and Canada. The study found:

- Cardiac survival was 77.9 percent at two years (with overall patient survival of 58.5 percent), and 68.0 percent at four years (with overall patient survival of 45.1 percent).
- At four years, patients saw substantial improvement in heart failure symptoms: While 87 percent were in NYHA Functional Class III or IV at the beginning of the study, most patients improved to Class I (61 percent) or Class II (22 percent) at four years. In addition, while nearly one-third of patients were classified as having grade 2 or 3 aortic regurgitation at baseline, all patients were classified as having no aortic regurgitation (57 percent) or grade 1 regurgitation (43 percent) at four years.
- Valve gradient (resistance to blood flow) decreased from 41 mmHg at baseline to 12 mmHg at 30 days and 10 mmHg at four years. Sustained, stable gradient is promising in that it shows the CoreValve performance does not diminish over a 4 year time frame.
- Valve performance was strong, with no reported frame fractures or valve migrations, and no reported structural valve deteriorations.

"These results reinforce that CoreValve is a sound and stable valve that holds up to real-world use," said Peter den Heijer, M.D., MPH, interventional cardiologist at Amphia Hospital Breda in the Netherlands and an investigator in the study. "Almost more important, however, is that these patients - most of whom were old and very sick at the time of enrollment - saw such positive outcomes, including dramatic improvements in the activity level they could withstand, despite being some of the first patients in the world to undergo TAVI."

The CoreValve System is designed to provide a minimally invasive treatment option - without open-heart surgery - for patients with symptomatic, severe aortic stenosis who are at high risk, or are ineligible, for open-heart surgery. Worldwide, approximately 300,000 people have been diagnosed with this condition, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery. Since 2007, the Medtronic CoreValve System has been implanted in more than 40 countries outside the U.S. The Medtronic CoreValve System is currently limited to investigational use in the United States; the Medtronic CoreValve System is not approved in Canada and is available there through the Special Access Programme.

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.

About Medtronic

Medtronic, Inc. (http://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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