Medtronic News

Largest Study of Medtronic CoreValve(R) System Confirms Positive Clinical Outcomes

CoreValve Italian Registry Results Demonstrate Clinical Benefits in a Real-World Patient Population

MINNEAPOLIS, Feb 18, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today issued a statement on results from an independent study published online in the journal *Circulation,* which confirmed both early and sustained clinical benefits for patients receiving the Medtronic CoreValve(R) System for the treatment of aortic valve disease. The article*, "Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis,"* discusses the largest CoreValve clinical study to date, with 663 consecutive aortic stenosis patients (mean age of 81 years) treated at 14 Italian centers beginning immediately after device commercialization in 2007. The article shows that patients receiving CoreValve have high rates of procedural success (98 percent), low rates of adverse events (2.1 percent) and substantial improvements of cardiac function.

The Medtronic CoreValve System is a minimally invasive, non-surgical treatment option for patients with requiring aortic valve replacement who are considered at high risk for surgery; CoreValve is delivered via transcatheter aortic valve implantation (TAVI) rather than open-heart surgery. The CoreValve system received CE (Conformité Européenne) Mark in March 2007 and has been implanted in more than 12,000 patients worldwide in 42 countries outside the United States. In the U.S., the CoreValve System is being evaluated in a U.S. Pivotal Clinical Trial.

"The positive results of our TAVI experience are encouraging and demonstrate positive clinical outcomes for a group of patients with few treatment options," said Corrado Tamburino, M.D., Ph.D., of Ferrarotto Hospital in Catania, Italy and principal investigator of the study. "Our findings demonstrate that a large majority of patients were treated successfully with CoreValve and experience improvements in heart function. This real-life registry gives further credence to this new therapy approach."

In this study, procedural success was 98 percent and intraprocedural mortality was 0.9 percent. Cumulative incidences of mortality were 5.4 percent at 30 days, 12.2 percent at 6 months, and 15 percent at one year. Additionally, the study reported low rates of permanent pacemaker implantation (16.6 percent at 2-weeks and 17.4 percent at 30-days). There also was substantial and sustained improvement in patients' health status, with 71.5 percent of patients in NYHA class III and IV before the implant achieving class I or II after the procedure.

The Italian Registry data also evaluated the incidence and predictors of early (30 days) and late (30 days to 1 year) mortality after TAVI. The authors concluded that while early mortality was strongly associated with procedural complications, late mortality was associated with co-morbidities (such as a prior stroke, a prior episode of acute pulmonary edema, or chronic kidney disease) and that pacemaker implant was not a factor.

"We welcome the robust findings from the Italian Registry, which substantially enhance the strong body of clinical evidence supporting the sustained clinical benefits of CoreValve in real-life clinical application," said John Liddicoat, M.D., vice president and general manager of the Structural Heart division at Medtronic. "We are committed to supporting clinical evaluation of the CoreValve system to offer patients with severe aortic stenosis the safest and most adequate technique for treating this disease."

About CoreValve

Approximately 300,000 people worldwide have been diagnosed with this severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery.1 The Medtronic CoreValve U.S. Pivotal Clinical Trial began in late 2010 and will enroll more than 1,300 patients at 40 U.S. clinical sites which are identified on www.clinicaltrials.gov. Additional information for patients and referring physicians can be found at www.aorticstenosistrial.com. CoreValve is not yet available in the U.S. for commercial sale or use.

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 lung et al. Eur Heart J (December 2005) 26(24): 2714-2720.

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