Medtronic News

Positive Clinical Outcomes Reported with Medtronic CoreValve(R) System

Meta-Analysis of Seven International Clinical Registries Presented at EuroPCR 2011 Late-Breaking Presentation

PARIS, May 20, 2011 (BUSINESS WIRE) --

A late-breaking presentation about transcatheter aortic valve implantation (TAVI) at EuroPCR 2011 today confirmed positive outcomes in patients receiving the CoreValve(R) System from Medtronic, Inc. (NYSE: MDT) across seven international clinical registries. The meta-analysis, undertaken by several leading international interventional cardiologists and presented during a late-breaking trial Hot Line session, summarized European data from 2,156 patients treated with the CoreValve System for severe aortic stenosis.

"Our weighted analysis of early and late clinical outcomes after CoreValve implantation demonstrates that this transcatheter self-expandable valve prostheses provides a safe treatment alternative to patients who are at high-risk or unable to undergo surgical aortic valve replacement," said Carlos E. Ruiz, M.D., Ph.D., director of the Structural and Congenital Heart Program at Lenox Hill Heart and Vascular Institute of New York. "There has been some variability in reported early and late outcomes with TAVI systems from individual country registries, which we believe can be attributed to limited sample sizes and different experience levels among physicians."

The results demonstrate positive patient outcomes based on procedural success rate (97.8 percent), vascular complication rate (2.9 percent), one-month stroke rate (1.9 percent), one-month survival rate (93.8 percent) and one-year all-cause mortality rate from five registries (17.1 percent).

The meta-analysis included findings from Australia, Belgium, France, Germany, New Zealand, Spain and the United Kingdom. Medtronic provided financial support for the meta-analysis. Limitations of the meta-analysis included use of non-standard definitions by independent registries and independent reporting of clinical outcomes.

The CoreValve System is designed to provide a minimally invasive, non-surgical treatment option 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 surgery1. 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.

**About Medtronic** 

Medtronic, Inc. (<u>www.medtronic.com</u>), 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.

SOURCE: Medtronic, Inc.

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