Medtronic News

Medtronic CoreValve(R) Multi-Center Study Shows Rapid and Sustained Health-Related Quality-of-Life Improvements

Two-year Results from Europe and Canada Represent Longest-term Quality-of-life Assessment of All Transcatheter Aortic Valves to Date

PARIS, May 17, 2011 (BUSINESS WIRE) --

New clinical data presented today at EuroPCR 2011 demonstrate immediate and long-term health-related quality-of-life (HRQoL) benefits for patients receiving the Medtronic CoreValve(R) System from Medtronic, Inc. (NYSE: MDT). The favorable two-year results from the 18-French CoreValve multicenter prospective study are the largest set of CoreValve HRQoL data and the longest-term HRQoL data available from all transcatheter aortic valve implantation (TAVI) systems.

"Together with positive two-year performance and durability data presented at EuroPCR 2010, these results offer clear, mounting evidence that CoreValve is a truly transformational therapy for many patients with severe aortic stenosis, resulting in sustained clinical benefits and improved quality of life," said Raoul Bonan, M.D., professor of medicine and interventional cardiology at Montreal Heart Institute in Montreal.

The study included 126 patients at nine centers in Europe and Canada who were implanted with the CoreValve system. Investigators reported the following HRQoL outcomes based on patient completion of the EuroQoL (EQ-5D) questionnaire and Visual Analog Scale (VAS) at baseline and after three, six, 12 and 24 months post-procedure:

- *Mean health utility scores (range 0-1)*: By 12 months, CoreValve patients reached the normal range of health utility scores (relative to UK general population norms for this age group) and this was sustained for 24 months. They improved from 0.60 at baseline to 0.71 at three months, 0.73 at 12 months and 0.76 at 24 months ($p<0.05$).
- *Visual Analog Scores (range 0-100):* Reflecting patients' improved perceptions of their health, these scores increased from 53.1 percent at baseline to 64.4 percent at 3 months, 67.3 percent at 12 months and 69.1 percent at 24 months ($p<0.0001$).
- *Pain/discomfort and anxiety/depression:* For individual patients, significant improvements were observed in these domains at three months and were maintained through 12 months ($p<0.05$).

The CoreValve System is designed to provide a non-surgical, minimally invasive 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. (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.

SOURCE: Medtronic, Inc.

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