

Medtronic CoreValve® System Demonstrates Long-Term Durability

March 31, 2014 6:30 AM CT



Final Follow-up of CoreValve CE Pivotal Study Shows Sustained Valve Function

MINNEAPOLIS - March 31, 2014 - Medtronic, Inc. (NYSE: MDT) today announced the final follow-up results from the CoreValve® CE Pivotal Study, which demonstrated excellent long-term durability at four years in patients with severe aortic stenosis who were treated with the self-expanding CoreValve System. The results were presented for the first time at the 63rd Annual Scientific Session of the American College of Cardiology.

The Study results showed the long-term durability and excellent clinical performance of the CoreValve System with no incidences of structural valve dysfunction at four years. The study also showed significant improvements in quality of life at one year which were sustained through four years, with 74 percent of patients improving at least one New York Heart Association (NYHA) functional class from baseline to four years. Additionally, the rates of regurgitation and stroke remained low, with 83.0 percent of patients free from stroke at four years follow-up.

Representing the first rigorous prospective evaluation of the CoreValve System and one of the first studies to report independent echocardiographic core laboratory-validated, long-term data for transcatheter valve durability, the CoreValve CE Pivotal Study enrolled 126 patients at nine centers throughout Europe and Canada. The study was designed to achieve CE (Conformité Européenne) Mark for the CoreValve System to treat patients who were considered too ill or frail to have their aortic valves replaced through traditional open-heart surgery.

"We are very encouraged by these long-term durability results for the CoreValve System, which supplement the exceptional clinical outcomes demonstrated through the U.S. pivotal trial," said Rhonda Robb, vice president and general manager of Catheter Based Therapies at Medtronic. "For patients needing a less invasive approach for aortic valve replacement, this therapy is showing great promise with high survival rates, low stroke rates and now reliable durability out to four years."

Presented earlier at ACC 2014, the High Risk Study of the CoreValve U.S. Pivotal Trial met its primary endpoint with a low one year, all-cause mortality rate of only 14.2 percent in patients receiving the CoreValve System, compared to 19.1 percent in patients receiving SAVR at one year (non-inferiority p -value<0.001; superiority p -value=0.04). The CoreValve High Risk Study is the first prospective, randomized study to show any transcatheter aortic valve to be superior to surgery.

The CoreValve System was designed specifically to overcome the challenges of a broad range of TAVR patients. The device has a small 18Fr profile for all valve sizes, which minimizes trauma at implant, and allows physicians to treat patients with small or calcified vasculature. Its Nitinol frame is designed to prevent unwanted leakage and optimize blood flow. In addition, the CoreValve System is available in the broadest range of sizes available, so patients who have smaller, larger or in-between sizes can be accommodated.

The CoreValve System was approved by the U.S. Food and Drug Administration (FDA) in January 2014 for patients considered extreme risk for surgery; the device is not currently approved in the U.S. for use with patients at high risk. Since receiving CE Mark in 2007, the CoreValve System has been implanted in more than 50,000 patients in more than 60 countries.

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. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

- end -

Contacts:

Kathleen Janasz
Public Relations
+1-763-526-3676

Jeff Warren
Investor Relations
+1-763-505-2696

HUG#1772728