Medtronic News

Medtronic Presents 30-Day Data on Valiant(R) Thoracic Stent Graft

Initial Results from U.S. IDE Study Demonstrate Early Safety and Effectiveness of Implantable Medical Device for Minimally Invasive Treatment of Thoracic Aortic Aneurysms

MINNEAPOLIS & NEW YORK, Nov 19, 2010 (BUSINESS WIRE) --

An implantable medical device used in the minimally invasive treatment of thoracic aortic aneurysms,the Valiant(R) Thoracic Stent Graft System from Medtronic, Inc. (NYSE: MDT), delivered strong results through 30 days of patient follow-up in the company's U.S. pivotal study, according to clinical data presented at VEITHsymposium(TM).

Approved by the U.S. Food and Drug Administration (FDA) under an investigational device exemption (IDE), the prospective, single-arm study involved 160 patients at 24 U.S. medical centers. Called VALOR II, the study was designed to evaluate the safety and effectiveness of the Valiant Thoracic Stent Graft System for thoracic endovascular aortic repair (TEVAR) for aneurysms in the descending thoracic aorta.

Through 30 days of follow up in VALOR II, rates of site-reported endoleaks were low: 0.7 percent for Type I, 3.4 percent for Type II, and 0.0 percent for both Type III and IV. In addition, no patients' treatment plans were converted from TEVAR to open surgery, and no patients experienced aneurysm rupture. The rate of all-cause mortality through 30 days was 3.1 percent.

"These compelling interim data from VALOR II show great promise for the Valiant Thoracic Stent Graft," said the study's principal investigator, Dr. Ronald Fairman, professor of surgery and chief of the division of vascular surgery and endovascular therapy at the Hospital of the University of Pennsylvania. "We look forward to seeing whether these results persist at the primary endpoint of 12 months and supply the evidence needed so that clinicians in the United States can use the Valiant Stent Graft in their practice."

The study's primary safety and effectiveness endpoints are 12-month all-cause mortality and 12-month successful aneurysm treatment, defined as the absence of aneurysm growth (>5 mm) at one and 12 months and type I and/or type III endoleak for which a secondary procedure was performed or recommended at or before the 12 month visit. The one-year results of VALOR II will be presented in mid-2011, along with unprecedented five-year TEVAR data from VALOR , the U.S. IDE study of Medtronic's Talent(R) Thoracic Stent Graft.

The Valiant Thoracic Stent Graft differs from the Talent Thoracic Stent Graft in several ways:

- The Valiant Thoracic Stent Graft is a modular device consisting of a polyester graft sutured to the outside (as opposed to the inside on the Talent Thoracic Stent Graft) of a self-expanding nitinol wire stent comprised of eight peaked springs stacked in a tubular configuration. With an outside suture, the raised surface of the springs provides additional mechanical interference when apposing to the aortic wall for improved sealing and fixation.
- The proximal and distal stent has an eight-peak crown (as compared to the five-peak configuration of the Talent Thoracic Stent Graft) that distributes radial force across more points of contact allowing for excellent sealing characteristics and a softer interface with the aortic wall.
- To increase graft flexibility and conformability, the longitudinal connecting bar of the Talent Thoracic Stent Graft has been eliminated in the Valiant Thoracic Stent Graft, and the spring spacing has been redesigned to allow adjacent peaks to contact each other and provide the necessary column strength for deployment.

The Valiant Thoracic Stent Graft System is currently used to treat patients with thoracic aortic aneurysms and injuries in more than 90 countries around the world. The leading thoracic stent graft outside the United States, it received the CE (Conformité Européene) mark in October 2009. The Valiant Thoracic Stent Graft System is an investigational device in the United States, where its clinical use is limited to studies approved by the FDA. VALOR II data will be used in Medtronic's submission to the FDA for pre-market approval (PMA) of the Valiant Thoracic Stent Graft System.

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists worldwide.

Now in its fourth decade, VEITHsymposium provides vascular surgeons, interventional radiologists, interventional cardiologists and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease.

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.

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