Medtronic News

VALOR II Study Highlights Strengths of Valiant(R) Thoracic Stent Graft from Medtronic

Innovative Medical Device Shows Strong Safety and Efficacy in Treatment of Thoracic Aortic Aneurysms Through One-Year of Patient Follow-Up in U.S. Clinical Study

MINNEAPOLIS & CHICAGO, Jun 18, 2011 (BUSINESS WIRE) --

An innovative 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 excellent clinical results through one year of patient follow-up in the company's U.S. pivotal study, VALOR II, according to data presented today at a meeting for vascular surgeons.

A thoracic aortic aneurysm (TAA) is a dangerous bulge in the body's main artery near where it branches off the heart; those that rupture usually result in death. An estimated 60,000 people in the United States alone have a TAA. Those that are detected before rupturing can usually be effectively treated with stent grafts or invasive surgery.

One-year results of the VALOR II study were presented today during a late-breaking clinical trials session at the annual meeting of the Society for Vascular Surgery by principal investigator Dr. Ronald Fairman, M.D., the Clyde F. Barker - William Maul Measey Professor of Surgery at the Hospital of the University of Pennsylvania, where he is chief of the division of vascular surgery and endovascular therapy, and the department of surgery's vice-chairman of clinical affairs. Attended by more than 1,500 vascular surgeons, the three-day 2011 Vascular Annual Meeting in Chicago ends today.

"The VALOR II 12-month results demonstrate that the Medtronic Valiant stent graft is a safe and effective treatment for patients with descending TAA of degenerative etiology," Dr. Fairman concluded. "Through 12 months, there were no cases of rupture or conversion to open surgery. Overall, treatment results were quite promising."

VALOR II is a prospective, single-arm study that involved 160 patients at 24 U.S. medical centers. It was designed to evaluate the safety and effectiveness of the Valiant Thoracic Stent Graft System for thoracic endovascular aortic repair (TEVAR) of aneurysms in the descending thoracic aorta.

The study met all of its prespecified endpoints. The primary safety and effectiveness endpoints were 12-month all-cause mortality and 12-month successful aneurysm treatment, defined as the absence of (a) aneurysm growth (>5 mm) at one and 12 months, and (b) type I and/or type III endoleak for which a secondary procedure was performed or recommended at or before the 12-month visit.

Through one-year of follow up in VALOR II, the rate of all-cause mortality was 12.6 percent, with only 3.3 percent of mortalities deemed aneurysm-related. Nearly all patients (97.4%) achieved 12-month successful aneurysm treatment, and very few stent grafts (2.9%) migrated from their original placement.

The Valiant Thoracic Stent Graft System is indicated for the endovascular repair of fusiform aneurysms, saccular aneurysms and penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including: iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories, non-aneurysmal aortic diameter in the range of 18-42 mm and non-aneurysmal aortic proximal and distal neck lengths greater-than or equal to 20 mm.

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.

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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