Medtronic News

Medtronic Presents One-Year Data on Endurant(R) Stent Graft

Definitive Results from U.S. IDE Study Demonstrate Durable Safety and Effectiveness of Implantable Medical Device for Minimally Invasive Treatment of Abdominal Aortic Aneurysms

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

An implantable medical device used in the minimally invasive treatment of abdominal aortic aneurysms, the Endurant(R) Stent Graft System from Medtronic, Inc. (NYSE: MDT), delivered strong results through one year 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 study involved 150 patients at 26 U.S. medical centers and met its primary endpoints. In the study, the Endurant System was associated with no post-operative aneurysm ruptures or aneurysm-related mortalities at one year, and there were no mortalities from any cause at 30 days.

"The clinical results with Medtronic's Endurant Stent Graft System out to one year in this study are quite encouraging," said the study's principal investigator, Dr. Michel Makaroun, M.D., professor and chief of vascular surgery for the University of Pittsburgh School of Medicine. "Based on this data, the Endurant Stent Graft, with its low-profile delivery system and accurate deployment, appears to be safe and effective in the short term. It will prove to be a great addition to the currently available devices in the management of abdominal aortic aneurysms for a wide range of patients."

The study's primary safety and effectiveness endpoints were major adverse events (MAE) at 30 days and a composite of technical and treatment success of the device at one year, respectively. Significantly for clinical practice, the study included patients with "landing zones," or healthy aortic neck lengths, as short as 10 mm, whereas most other trials of aortic stent grafts have required neck lengths of at least 15 mm.

The study monitored changes in aneurysm size and stent graft migration, a concern with current endovascular treatment. Nearly half (47.1 percent) of the aneurysm sacs that were treated with the Endurant Stent Graft System in the study decreased in size between one month and one year post-procedure, and none of the sacs increased in size; the rest (52.9 percent) remained stable in size during the same time period. In addition, none of the stent grafts migrated from their original placement.

The study also monitored the occurrence and type of endoleaks, which can result in persistent blood flow into the aneurysm sac. Through one year post-implant, there were no (zero) Type I or III endoleaks.

The Endurant Stent Graft System is currently used to treat patients with abdominal aortic aneurysms in approximately 100 countries around the world. The leading abdominal stent graft outside the United States, it received the CE (Conformité Européene) mark in July 2008. The Endurant System is an investigational device in the United States, where its clinical use is limited to studies approved by the FDA. It is currently under review by the FDA for pre-market approval (PMA).

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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