Medtronic's Endurant AAA Stent Graft Delivers Durable Outcomes for Abdominal Aortic Aneursym Repair

The Associated Press

Two-Year Clinical Data Presented at VEITHsymposium Demonstrate Consistently Strong Performance Worldwide in Pre- and Post-Market Evaluations of Innovative Medical Device

MINNEAPOLIS -- Nov. 19, 2012 -- Chosen for nearly one out of every two endovascular abdominal aortic aneurysm repairs worldwide, the Endurant AAA stent graft system from Medtronic, Inc. (NYSE: MDT) continues to show robust results in mid-term follow-up, according to two-year clinical data presented at VEITHsymposium, which concluded yesterday in New York.

The latest evidence on the market-leading stent graft comes from two clinical evaluations with two years of patient follow-up -- the U.S. investigational device exemption (IDE) study and the international ENGAGE registry, the largest collection of data on any single commercially available stent graft.

The U.S. IDE study of the Endurant system enrolled 150 patients at 26 U.S. centers and led to the device's approval by the U.S. Food and Drug Administration (FDA) in December 2010. The international ENGAGE registry has enrolled more than 1,200 patients at more than 80 sites across six continents since the Endurant system received the CE (Conformité Européenne) mark in June 2008.

"It's reaffirming to see that the two-year data from the international ENGAGE registry and the U.S. IDE study are similar to what we saw at one year, which indicates that the Endurant AAA stent graft continues to perform well in a variety of geographic locations and patient anatomies," said ENGAGE investigator Dittmar Bockler, MD, PhD, of the University Hospital of Heidelberg in Germany, who shared these results at VEITHsymposium on Saturday. "The Endurant system sets a new standard in clinical outcomes for aortic stent grafts with unprecedented breadth, depth, quality and consistency of results."

International ENGAGE Registry Two-year results on 500 patients from the international ENGAGE registry showed that more than 98 percent (490 patients) were free from aneurysm-related mortality through two years of post-procedure follow-up. The Type I/III endoleak rate was low (1.1 percent) for this real-world patient population, with more than half (56 percent) of the aneurysm diameters among these 500 patients showing a reduction in size of 5 mm or more.

U.S. IDE Study Demonstrating similar safety and efficacy, two-year results on all

150 patients from the U.S. IDE study showed 100 percent freedom from aneurysm-related mortality. Additionally, the Type I/III endoleak rate was low (0.8 percent), with more than three-fifths (62 percent) of the aneurysm diameters decreasing by at least 5 mm.

Two-Year Outomes with Endurant AAA Stent Graft
Notable Clinical Endpoints ENGAGE Registry (N=500 Patients) U.S. IDE Study (N=150 Patients) Freedom from ARM* 98.1% 100% Type I/III Endoleak 1.1% 0.8% Aneurysm Diameter Reduction 56% 62%
* Aneurysm-related mortality (ARM) is defined as death from rupture or from any procedure intended to treat the aneurysm.

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.

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 [1]), 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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Contacts: Joe McGrath Public Relations +1-707-591-7367 Jeff Warren Investor Relations +1-763-505-2696

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[1] http://www.medtronic.com