Medtronic News

Medtronic Demonstrates Commitment to EVAR in Comparison Study of ENGAGE Global Registry and Landmark EVAR 1 Trial

Clinical Integrity on Display through Longest Term Data of 1,200 Endurant AAA Stent Graft Patients

DUBLIN AND LONDON - April 27, 2016 - Medtronic plc (NYSE:MDT) today reported on the ENGAGE global registry of experiences with the Endurant® AAA stent graft system from Medtronic with a reference to the landmark EVAR 1 Trial. ENGAGE represents the most robust post-market registry ever initiated in the study of endovascular aortic repair (EVAR) with more than 1,200 patients at 79 sites across six continents and ten-year follow-up planned for all patients. A decade ago in a breakthrough conclusion, EVAR 1 demonstrated better aneurysm-related survival for EVAR over open surgery. Today's comparison comes from a presentation at the 2016 Charing Cross Symposium in London.

Professor Roger Greenhalgh, M.D., Charing Cross chairman and author of the EVAR 1 Trial stated, "The EVAR 1 trial is the world's first randomized, controlled trial of EVAR compared with open repair using devices implanted between 1999 and 2005. It is therefore an appropriate benchmark against which newer generation devices can be compared."

Dittmar Böckler, M.D., University of Heidelberg, Department of Vascular Surgery in Germany and ENGAGE investigator today presented ENGAGE registry outcomes with reference to EVAR 1.

Aneurysm-related mortality was 1.6 percent in the ENGAGE registry through four years.1 EVAR 1 reported aneurysm-related mortality of 3.5 percent for EVAR and 6.3 percent for open surgery.2 The ENGAGE Registry also reported a lower rupture rate than in EVAR 1, as well as a decreased secondary intervention rate.

"In the comparison analysis of ENGAGE and EVAR 1 we can see just how far our medical advancements have come in improving patient outcomes with EVAR," said Prof. Böckler. "The very well-structured EVAR 1 gave us the opportunity to understand the urgent need of improvement in EVAR, especially in mid- and long-term endograft behavior. Thanks to large real world registries, such as ENGAGE, we can do scrupulous analysis of different subgroups' outcomes. The commitment from Medtronic to support a robust large scale registry is the type of clinical rigor that interventionalists have come to rely on and will propel us into the future in treating more challenging anatomies with minimally invasive options and long-term durability."

Selected for nearly one of every two endovascular abdominal aortic aneurysm (AAA) repairs globally and more than 200,000 successful implants, the Endurant system received the CE (Conformité Européenne) Mark in June 2008. U.S. Food and Drug Administration (FDA) approval was received in December 2010. The Endurant stent graft system is approved outside of the U.S. for use in patients with AAA neck lengths >=10 mm and <=60° infra-renal angulation and >=15mm with <=75° infra-renal angulation. In the U.S., the Endurant stent graft system is indicated for necks >=10 mm and <=60° infra-renal angulation. At the 2015 VEITHsymposium, ENGAGE registry data demonstrated that the Endurant AAA Stent Graft delivers durable, consistent and proven outcomes at four years in real-world settings.

"Medtronic's commitment to improving patient outcomes through clinical rigor is unsurpassed," said Daveen Chopra, vice president and general manager of the Aortic business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "As the leader in EVAR, we continue to build upon our success and learnings from ENGAGE to treat more complex aortic 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 plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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1 Veith Symposium, 2015: Medtronic data on file

2 Lancet. 2005 Jun 25-July 1; 365 (9478): 2179-86

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