Medtronic News

Medtronic's Endurant(TM) II/IIs Stent Graft System Delivers Positive Outcomes in Patients with Challenging Aortic Aneurysms

New Data from the Global ENGAGE Registry Builds on Durability of Endurant, with Strong Outcomes Out to Four Years in Patients with Standard and Hostile Neck Anatomies

DUBLIN - Nov. 15, 2016 - Medtronic plc (NYSE:MDT) today announced data supporting the strength and durability of the Endurant(TM) II/IIs1 stent graft system to treat abdominal aortic aneurysm (AAA) patients. The results, presented during the 43rd Annual Symposium of Vascular and Endovascular Issues (VEITHsymposium) in New York, are based upon new sub-analyses of Medtronic's ENGAGE Global Registry, which has enrolled more than 1,200 patients at 79 sites across six continents. With 10-year follow-up planned for all patients, ENGAGE represents the most robust post-market registry ever initiated in the study of endovascular aortic repair (EVAR).

Created with the collaboration of physicians around the world, the Endurant stent graft system treats AAA using EVAR. While EVAR is used widely for patients with standard anatomy, patients with challenging anatomy have historically been difficult to treat, and are associated with limited eligibility for endovascular repair and higher rates of secondary interventions.

In a sub-analysis of ENGAGE presented for the first time, Prof. Hence Verhagen, M.D., Ph.D., chief of vascular surgery at Erasmus University Medical Center in Rotterdam, the Netherlands, reviewed the use of EVAR in patients with both standard and complex anatomies emphasizing Type Ia endoleaks (an endoleak characterized by a poor seal at the aortic neck). In a compelling finding based on the full registry cohort (n=1263), patients were free from Type Ia endoleaks for up to four years, with rates of 97.8 percent (one year), 97.3 percent (two years), 96.7 percent (three years), and 96 percent (four years). Similar results were seen in sub-analyses of both standard and complex patients at all time points.

"The impact of a Type Ia endoleak is serious and includes an increased risk of rupture and the need for reintervention. This new analysis from the four-year global ENGAGE registry provides further evidence of the benefits of EVAR in patients with both standard and complex anatomies, and it reflects the low endoleak rates that can be achieved with the Endurant stent graft system," said Prof. Verhagen.

A second sub-analysis of the ENGAGE registry data presented by Prof. Verhagen is one of the largest to date of long-term outcomes in patients (n>100) with hostile aortic neck anatomy (highly angulated, conical and circumferential thrombus/calcium). The results showed that Endurant achieves positive results in patients with various hostile neck types followed up to four years. At four years these mid-term outcomes, such as aneurysm related mortality, rupture and conversion to open surgical repair, offer clinical insight into the treatment of AAA neck anatomies that is relevant and applicable to current clinical practice and real-world settings. "Data from the ongoing global ENGAGE registry show positive outcomes in several anatomically challenging sub-groups, including those with hostile aortic necks," continued Prof. Verhagen.

Additionally, Prof. Dittmar Böckler, M.D., University of Heidelberg, Department of Vascular Surgery in Germany and ENGAGE investigator, reviewed data from the ENGAGE registry outcomes with reference to the flagship EVAR 1 study.2 These results, which were first presented at Charing Cross Symposium in April 2016, showed that Endurant was more effective than the previous generation of endografts evaluated in EVAR1, with a 54 percent relative risk reduction in aneurysm-related mortality rates (ARM), a 44 percent relative risk reduction of rupture, and a 35 percent relative risk reduction in secondary interventions. The findings support utilization of Endurant in a wide range of patients.

"The Endurant stent graft system is a great example of Medtronic's commitment to work together with clinicians to provide patients with clinically driven, life-saving technology. With more than 250,000 successful implants, our leadership in EVAR is

supported by deep clinical experience," said Daveen Chopra, vice president and general manager of the Aortic business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "The data from the ENGAGE registry presented at VEITHsymposium adds to the unmatched clinical experience of Endurant, further demonstrating why it provides physicians with a durable and effective solution to treat more patients, including those with both standard and complex anatomies."

About Endurant Stent Graft System

Selected for nearly one of every two endovascular AAA repairs globally and used in more than 250,000 successful implants, the Endurant stent graft system has been approved in the U.S. since December 2010. In the U.S., it is indicated for necks >=10 mm and <=60° infra-renal angulation and >=15mm with <=75° infra-renal angulation. Since the original Endurant system received CE Mark approval in June 2008, the ENGAGE registry has enrolled more than 1,200 patients.

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 VEITHsymposium

Now in its 43rd year, 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. The 5-day event features rapid-fire presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques. Press will receive complimentary registration. Please visit www.VEITHpress.org or contact Pauline T. Mayer at +1-561-316-3330.

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 88,000 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 In the U.S., the Endurant II/IIs stent system is approved for neck lengths >=10 mm and <=60° infra-renal angulation.

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

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