Medtronic News

New Five-Year Gender Subset Data from the Medtronic Engage Registry Presented in VIVA Late Breaking Trials

Five-Year, Real-World Data Demonstrate EVAR Outcomes with Endurant® II Stent Graft System Are Comparable in Both Male and Female Patients

DUBLIN and LAS VEGAS - September 13, 2017 - Medtronic plc (NYSE: MDT) today reported its Endurant® II abdominal aortic aneurysm (AAA) stent graft system continues to demonstrate long-term durability and consistent outcomes in a real-world setting among both male and female patients. The five-year ENGAGE global registry data were presented for the first time by Marc Schermerhorn, M.D., chief, division of vascular and endovascular surgery, Beth Israel Deaconess Medical Center, Boston, Mass., in a late-breaking clinical trial at the Vascular Interventional Advances (VIVA) 2017 conference in Las Vegas.

Women have historically demonstrated worse EVAR outcomes than men due to differences between the female and male anatomies, including shorter, more angulated aortic necks, smaller aneurysms, and smaller iliac vessels. Female patients also have historically demonstrated higher rates of mortality, access complications, and endoleaks compared to men.

"It is well known in the clinical community that women have not benefitted to the same extent as men when receiving an EVAR procedure, and in turn, have become a greatly underserved patient population," said Dr. Schermerhorn. "Endurant is now the only stent graft system to close the outcomes gap between men and women at 30 days, one year, and five years, which sets a new benchmark for EVAR device performance and has the potential to change the treatment paradigm for female patients."

The five-year gender subset analysis of the ENGAGE global registry included 1,263 patients (133 female and 1,130 male). The study population was comprised of females with an average age of 75.7 years with smaller diameter proximal necks and narrower access vessels. Approximately 16.5 percent of females compared to 11.5 percent of males had proximal neck lengths <15mm and 19.7 percent of females compared to 9.0 percent males had infrarenal neck angles of >60 degrees. The data underscore previous findings between men and women at 30-days and one-year, which demonstrated consistent efficacy and safety.

The five-year data demonstrated a successful delivery and deployment rate of 99.2 percent in the female cohort compared to 99.5 percent in the male cohort (p=0.746). The study also showed consistency between genders, with:

- A freedom from aneurysm-related mortalities (ARM) in females of 100.0 percent compared to a 97.5 percent freedom from ARM in males (p=0.0881)
- Type Ia endoleaks were observed in 3.8 percent of females compared to 1.3 percent of males (p=0.197) at five years
- A freedom from secondary procedures in females of 85.6 percent compared to 84.1 percent freedom from secondary procedures in males (p=0.5150)
- Aneurysm sac stable or decrease was observed in 89.6 percent of females compared to 89.4 percent of males at five years
- A freedom from rupture rate in females of 100.0 percent compared to a 98.4 percent freedom from rupture rate in males (p=0.2263)

ENGAGE represents the most robust post-market registry ever initiated in the study of EVAR with 79 sites in 30 countries. The ENGAGE registry was initiated less than one year post CE Mark and will have clinical follow up out to 10 years, further demonstrating the Medtronic commitment to long-term clinical excellence. The goal of

ENGAGE remains to gather evidence in a real-world patient population, including patients with challenging anatomy who have historically been difficult to treat, and are associated with limited eligibility for endovascular repair and higher rates of secondary interventions.

"Our objective has always been to deliver proven, durable solutions that effectively address varying patient anatomies and yield long-term clinical outcomes," said Daveen Chopra, vice president and general manager of the Aortic business in Medtronic's Cardiac and Vascular Group. "The newly presented clinical evidence from ENGAGE truly underscores this objective and validates that Endurant is able to deliver similar technical and long-term clinical outcomes between genders through five years, despite significantly challenging female anatomy."

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About the Endurant II/IIs Stent System

Selected for nearly one of every two endovascular abdominal aortic aneurysm (AAA) repairs globally in the past five years and more than 280,000 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.

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 84,000 people worldwide, serving physicians, hospitals and patients in more than 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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