Medtronic News

Five-Year Data from the Medtronic ENGAGE Registry Demonstrate Durable, Consistent, and Proven Outcomes in Real-World Setting

Presented at Charing Cross, Five-Year Clinical Data from Global ENGAGE Registry Support Endurant II's Market-Leading Position Worldwide

DUBLIN and LONDON - April 26, 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. The five-year ENGAGE global registry data were presented for the first time at the 2017 Charing Cross Symposium in London.

The ENGAGE registry evaluated more than 1,200 patients. The five-year data, which included imaging follow up from approximately 500 of these patients, showed a 97.8 percent freedom from aneurysm-related mortality (ARM) and a compelling 89.4 percent stable or decrease diameter AAA sac at five years. The data demonstrated an 84.3 percent freedom from secondary endovascular procedures.

"Out to five years, the ENGAGE data showed low ARM and secondary procedure rates. This further demonstrates both the benefit of the technique used with Endurant as well as the durability of the graft itself," said ENGAGE investigator Philippe Cuypers, M.D., Ph.D., vascular surgeon, Catharina Hospital in Eindhoven, The Netherlands, who presented the data. "The clinical rigor and scope of the ENGAGE registry has made it a valuable data set that represents the types of challenging anatomies physicians encounter in daily clinical practice."

ENGAGE represents the most robust post-market registry ever initiated in the study of endovascular aortic repair (EVAR) with 79 sites in 30 countries. The ENGAGE registry was initiated less than one year post CE Mark and has 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. A rigorous monitoring protocol has resulted in a clinical follow-up compliance of more than 90 percent and imaging compliance of more than 75 percent at five years.

Data from ENGAGE Featured in Other Key Presentations at Charing Cross

The Endurant stent graft system was also featured in an additional presentation that showcases how the ENGAGE data are being used to inform clinician's treatment decisions following EVAR procedures. On Wednesday, April 26, 2017, Peter Holt, M.D., senior lecturer and honorary consultant in vascular surgery at St. George's University of London presented the design of the LEAR analysis, which aims to reduce long-term aortic risk using a modified clinical surveillance program that more accurately portrays reintervention risk.

As demonstrated in Prof. Hence Verhagen, M.D., Ph.D., presentation entitled "Safety Considerations with Hostile Neck 10-15mm," on April 26, 2017, Endurant continues to demonstrate durable results across a range of patient anatomies, including patients with more hostile aortic necks, which have historically been associated with limited eligibility for endovascular repair and higher rates of adverse events.

"Medtronic aims to increase access to treatment for patients with Aortic disease. This goal has been reinforced by our commitment to developing robust clinical programs - such as the ENGAGE registry - that help clinicians identify durable treatment options," said Daveen Chopra, vice president and general manager of the Aortic business in Medtronic's Cardiac and Vascular Group. "In fact, we are leveraging our strong Endurant stent graft data for a pilot risk-share program in the U.S. that has been designed to help decrease customer costs associated with secondary EVAR interventions."

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 the Endurant II/IIs Stent System

Selected for nearly one of every two endovascular abdominal aortic aneurysm (AAA) repairs globally 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 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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