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Medtronic announces first enrollment in head-to-head global randomized trial evaluating durability of endovascular aneurysm repair

ADVANCE Trial compares sac regression in the Medtronic Endurant™ II/IIs stent graft system and the Gore® Excluder®* AAA Device Family systems

Medtronic today announced the first patient enrollment in the ADVANCE Trial, a head-to-head randomized controlled trial of two leading aortic stent graft systems, the Medtronic Endurant II/IIs stent graft system and GORE Excluder AAA Device Family systems. The ADVANCE Trial is a global, post-market, prospective, interventional, multicenter, randomized study that will enroll a minimum of 550 patients at up to 50 centers globally. Patients will be randomized to receive endovascular aneurysm repair (EVAR) with either the Endurant family or Excluder family grafts and will be followed at one month, one year, and annually through five years.

The first patient in the ADVANCE Trial was enrolled by the team led by Ray Workman, MD, at Novant Health Forsyth Medical Center in Winston-Salem, North Carolina.

“Through the ADVANCE Trial, we are working to deepen our evidence of sac regression as a key indicator of long-term EVAR patient outcomes,” said Prof. Hence Verhagen, Professor of Vascular Surgery, head of Vascular Surgery Erasmus MC, Rotterdam, Netherlands, and co-principal investigator of the trial. “Our hope is that the findings will allow physicians to make evidence-based clinical decisions to improve long-term patient outcomes.”

The ADVANCE Trial aims to further the understanding of sac regression by robust evaluation of CT imaging utilizing an independent core lab through five years. The trial will provide a comparison of aneurysm sac regression outcomes between the Medtronic Endurant II/IIs stent grafts and the GORE Excluder AAA Device Family stent grafts with additional evidence to analyze risk factors related to aneurysms that fail to regress. The trial will also compare other key clinical outcomes between the two stent grafts, including endoleaks, migration, secondary interventions, mortality, and renal complications.

“We are pleased to announce the first patient enrolled in the ADVANCE Trial,” said Marc Schermerhorn, MD, Chief of Vascular and Endovascular Surgery, Beth Israel Deaconess Medical Center in Boston, Massachusetts, and co-principal investigator of the trial. “This milestone underscores the commitment to rigorous study of the long-term data around the durability of the Endurant system for patients in need of EVAR. The results of the trial aim to

demonstrate contemporary outcomes and our overarching goal to deliver superior aortic patient care through robust and rigorous clinical data."

The ADVANCE Trial draws on clinical data showing that one-year sac regression is an early indicator of improved long-term survival.[2] The outcomes were consistent with the eight-year results from the ENGAGE OUS Registry, published in January 2022, which demonstrated the long-term clinical safety and effectiveness of the Endurant Stent Graft System.[3] The ENGAGE OUS Registry followed subjects through 10 years.

The Endurant II/IIs bifurcated stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. Endovascular stent grafting may be an option for patients who have an abdominal aortic aneurysm as determined by a vascular specialist.

An abdominal aortic aneurysm (AAA) is a localized bulging or enlargement of the abdominal aorta, a condition impacting more than 2.4 million people globally.[1] EVAR is a minimally invasive alternative to major open surgery for the repair of AAAs, performed using an abdominal stent graft. Current research demonstrates that sac regression (the reduction or shrinkage in the aneurysm diameter as a result of EVAR) is associated with better long-term outcomes, including mortality and secondary reinterventions.[2]

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.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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[1] Patient Access Acceleration Report. Medtronic data on file, 2019.

[2] O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg. February 2019;69(2):414-422.

[3] Teijink J, Power A, van Sterkenburg S, et al. 8-Year Data from the ENGAGE Registry Extension: Insights About the Long-term Performance of a Contemporary EVAR Device. Presentation presented online at: ESVS 35th Annual Meeting. September 20, 2021.

https://news.medtronic.com/durability-of-endovascular-repair