Medtronic Begins Enrollment in Feasibility Study of Valiant 'Mona LSA' Branch Thoracic Stent Graft System

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Investigational Device Enables Endovascular Repair of
Aortic Aneurysms Encroaching on Left Subclavian Artery

DUBLIN -- April 21, 2015 -- Medtronic plc (NYSE: MDT) today announced the start of a new feasibility study to evaluate the safety and effectiveness of the Valiant Mona LSA branch thoracic stent graft system, an investigational medical device designed to enable a completely endovascular solution for aortic aneurysms encroaching on the left subclavian artery (LSA).

Cleveland Clinic cardiothoracic surgeon Dr. Eric Roselli successfully completed the first implant in the study on Thursday. He serves as the study's national primary investigator and receives consulting fees and honoraria for teaching from Medtronic.

"Thoracic aortic aneurysms involving branch vessels such as the LSA can be particularly challenging to treat," Dr. Roselli said. "The use of an off-the-shelf stent graft system with a built-in branch has the potential to simplify this challenge by eliminating the routine requirement for surgical LSA bypass."

The study aims to enroll 24 subjects at up to seven sites in the United States. The purpose of the study is to characterize the safety and effectiveness of the investigational device acutely and at 30 days.

The LSA branches off the arch of the aorta and supplies oxygenated blood to the posterior brain and left arm. Coverage of the LSA during endovascular repair of thoracic aortic aneurysms proves necessary in about 40 percent of cases and is associated with a higher rate of neurological complications, according to published reports in peer-reviewed medical journals. As a result, the Society for Vascular Surgery suggests routine revascularization of the LSA in elective cases where achievement of an adequate seal zone for the stent graft requires coverage of the LSA.[i]

Based on the market-leading Valiant Captivia thoracic stent graft system, which has been used to treat approximately 50,000 patients worldwide over the last 10 years, the Valiant Mona LSA system consists of two pieces -- a main graft for placement in the aneurysmal segment of the aorta, and a branch graft for placement in the LSA. In their deployed state, the system's two pieces fit together to exclude the aneurysm and maintain patency of the LSA. The main graft features a tapered opening, or cuff, which is oriented toward the LSA. The branch graft fits inside the cuff and terminates in the LSA.

"The start of this study represents another step forward in our efforts to develop standardized stent graft systems for the treatment of aortic disease involving branch vessels," said Daveen Chopra, vice president and general manager of the Aortic franchise in Medtronic's Aortic and Peripheral Vascular business. "We remain committed to innovating safe and effective endovascular solutions for these complex clinical challenges in support of vascular interventionalists and their patients around the world."

The Valiant Mona LSA system has previously been studied as part of an early feasibility pilot program for medical devices initiated by the U.S. Food and Drug Administration (FDA) in 2012. It was one of nine devices selected by the FDA for the program. Results from this previous evaluation were presented at the VEITHsymposium.

Use of the Valiant Mona LSA branch thoracic stent graft system is limited to the current study approved by the U.S. Food and Drug Administration (FDA) under an investigational device exemption (IDE).

In collaboration with leading clinicians, researchers, and scientists, Medtronic offers the broadest range of innovative

medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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i The Society for Vascular Surgery Practice Guidelines: Management of the left subclavian artery with thoracic endovascular aortic repair. J Vasc Surg 2009; 50:1155-8

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