Medtronic Starts Clinical Study of Endurant Evo AAA Stent Graft System for Endovascular Treatment of Abdominal Aortic Aneurysms

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Principal Investigators Perform First Implant of Investigational Medical Device Designed to Expand Applicability of Minimally Invasive Alternative to Open Surgical Repair

DUBLIN -- April 27, 2015 -- Medtronic plc (NYSE: MDT) recently began a clinical study to evaluate the safety and effectiveness of the Endurant Evo AAA stent graft system, an investigational medical device designed to expand the applicability of a minimally invasive alternative to open surgical repair for the treatment of abdominal aortic aneurysms.

Based on the market-leading Endurant platform, the Endurant Evo AAA stent graft system features an evolved design that aims to simplify the implant procedure and increase patient customization options.

The study's two principal investigators -- Prof. Gilbert R. Upchurch, Jr., MD, chief of vascular and endovascular surgery at the University of Virginia in Charlottesville, Va., and Prof. Hence Verhagen, MD, PhD, chief of vascular surgery at Erasmus Medical Center in Rotterdam, The Netherlands -- collaboratively performed the first implant of the low-profile device last week at the University of Virginia (UVA). They were assisted by Saher Sabri, MD, an assistant professor from UVA's Division of Interventional Radiology. The patient, a 56-year-old man, had an abdominal aortic aneurysm (AAA) with a 5.05 cm diameter.

"The first clinical use of the Endurant Evo AAA stent graft system went well," said Prof. Upchurch, the study's U.S. principal investigator. "Insertion and deployment were simple and straightforward."

Prof. Verhagen, the study's European principal investigator, added: "The Endurant Evo AAA stent graft system has a variety of design features that have the potential to make endovascular repair of abdominal aortic aneurysms an option for more patients. "That potential is what's most exciting to me about this study."

The study will enroll 140 patients with infrarenal abdominal aortic or aortoiliac aneurysms at up to 30 sites in the United States and Europe. All study patients will be treated with the Endurant Evo AAA stent graft system.

The study's primary safety endpoint is defined as the proportion of subjects experiencing a major adverse event within 30 days post-implantation; its primary effectiveness endpoint is defined as the proportion of subjects with both technical success at the time of the index procedure and treatment success at 12 months post-implantation.

Clinical evidence from the study will be used to seek regulatory approvals required to commercialize the Endurant Evo AAA stent graft system in the United States and other markets around the world.

The Endurant Evo AAA stent graft system includes the following design features:

- a 3 French reduction in profile facilitates vascular access
- in-situ sizing with a three-piece system and adjustable limb length simplifies pre-case planning and reduces inventory
- an enhanced delivery system eliminates the tip-recapture step and incorporates an integrated flush port for contrast injection
- smaller leg diameters and helical limb stents expand patient applicability in tight distal aortas and tortuous iliac arteries
- multiple aortic body lengths and a larger range of limb lengths and diameters improve patient customization

"Medtronic is committed to improving the detection and treatment of aortic disease globally," said Daveen Chopra, vice president and general manager of the Aortic franchise at Medtronic. "The Endurant Evo AAA stent graft system provides another proof point for our enduring commitment to invest in innovation for the endovascular treatment of complex aortic disease."

As an investigational medical device, the Endurant Evo AAA stent graft system may only be used in the current clinical study, which has been approved by the U.S Food and Drug Administration (FDA) and similar European regulatory bodies.

Medtronic is the long-standing leader in medical technology for endovascular aortic repair. Medtronic stent grafts have been used to treat more than 400,000 patients worldwide since 1999 -- more than those from any other company. Nearly one of every two stent grafts used to treat an abdominal aortic aneurysm is made by Medtronic.

ABOUT ABDOMINAL AORTIC ANEURYSMS
An abdominal aortic aneurysm (AAA) is a localized bulge in the wall of the aorta, the body's largest artery, where it traverses the abdomen. The condition occurs mostly in older people and more commonly in men than women. It is present in approximately 1.2 million people in the United States alone, but often goes undiagnosed due to lack of symptoms.

Undetected or untreated, AAAs can expand and eventually rupture, an emergency situation involving extensive internal bleeding that usually results in death. They are responsible for approximately 15,000 deaths annually in the Unites States. Ruptured AAAs are the country's third leading cause of sudden death in men over age 60.

Risk factors for an AAA include advanced age, male gender, hypertension, high cholesterol, smoking (past or present), atherosclerosis, and a family history of AAA. People with multiple risk factors should ask their doctor about an abdominal ultrasound screening, which is a quick, easy, inexpensive and noninvasive imaging technique that can be used to determine the presence and size of an AAA.

AAAs are among the most preventable causes of death because they are highly treatable. Treatment options include open surgical repair and endovascular repair.

Open surgical repair requires an incision from the bottom of the breastbone to the top of the pelvic bone to expose the aneurysm. The surgery replaces the aneurysmal segment of the aorta with a fabric tube, or graft, which is sewn into place to restore blood flow.

Endovascular repair involves a keyhole procedure in which a stent graft -- a wire frame (stent) attached to a fabric tube (graft) -- is delivered in a compressed state through a catheter, which is inserted into an artery in the upper leg and navigated to the site of the aneurysm, where it is deployed from inside the aorta. The stent graft creates a new path for blood flow, reducing pressure on the aneurysm and the risk of rupture.

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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