Medtronic News

Medtronic Launches ENCHANT Study to Evaluate ChEVAR Parallel Graft Technique with the Endurant(TM) II/IIs Stent Graft System

Clinical Study to Investigate the Performance of the ChEVAR Technique in AAA Patients with Short Aortic Necks

DUBLIN - January 24, 2018 - Medtronic plc (NYSE: MDT) today announced the launch of the ENCHANT (ENdurant CHEVAR New Indication Trial) study. The post-market, non-interventional, multi-center, non-randomized, single-arm study will enroll approximately 150 patients across 25 sites in Europe and Russia, and will evaluate the safety and performance of a ChEVAR procedure using the Endurant(TM) II/IIs stent graft system in a real-world setting. The first enrollment at St. Franziskus Hospital in Munster, Germany, was led by Professor Giovanni B. Torsello, M.D., chief of Vascular Surgery and principal investigator for the ENCHANT study.

A ChEVAR procedure refers to the use of a parallel graft chimney technique that uses covered renal stents with a standard aortic stent graft. The study is the first to assess the clinical outcomes, safety, and performance of the ChEVAR technique for treating patients with complex aneurysms with short infrarenal neck lengths of >=2 mm in a real-world setting.

"We are excited to initiate this study in a real-world population, which will build upon existing clinical evidence for the ChEVAR technique as a standardized approach for treating short infrarenal necks," said Prof. Torsello, M.D. "We believe the study marks another significant milestone for patients with complex forms of aortic disease who, until recently, had not been suitable for a minimally-invasive endovascular procedure."

The ENCHANT study's primary safety endpoint is major adverse events through 30 days post-index procedure. The primary performance endpoint is the proportion of enrolled patients who have technical success at the time of the index procedure and are free from secondary interventions through 365 days.

"As the only stent graft company with a ChEVAR indication, we are deeply invested in delivering solutions, in partnership with the clinical community, that are backed by clinical rigor and address the unmet needs of AAA patients," said Daveen Chopra, vice president and general manager of the Aortic business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "This is the first industry-sponsored study to evaluate the ChEVAR technique in this patient population, and is another testament of our ongoing commitment to innovation in complex aortic disease and superior clinical outcomes."

The Endurant II/IIs stent system received CE (*Conformité Européenne*) Mark for a ChEVAR indication in December 2016. The approval was supported by the PROTAGORAS study, which demonstrated that standardized use of the Endurant II/IIs stent graft system with ChEVAR in 128 patients is associated with 100 percent technical success, statistically significant aneurysm sac regression ($p = .001$), 95.7 percent primary patency of the chimney grafts and a low incidence of chimney related reinterventions.

The Endurant II/IIs stent graft system is based on Medtronic's leading Endurant stent graft system, which for the last five years, has been selected for nearly one of every two endovascular AAA repairs globally and has resulted in more than 300,000 successful implants. The original Endurant system received the CE Mark in June 2008. In the U.S., Food and Drug Administration approval for the Endurant stent graft system was granted in December 2010. In the U.S., the Endurant II/IIs stent system is approved for neck lengths >=10 mm and <=60° infra-renal angulation.

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 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 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.

-end-

Contacts:

Julia Baron
Public Relations
+1-858-692-2001

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2018-01-24-Medtronic-Launches-ENCHANT-Study-to-Evaluate-ChEVAR-Parallel-Graft-Technique-with-the-Endurant-TM-II-IIs-Stent-Graft-System