Medtronic News

Medtronic Begins Real-World Post-Market Study of the Valiant Navion Thoracic Stent Graft System in Patients with Thoracic Aortic Dissection

Global "DISSECT-N" Post-Market Study to Broaden Evidence Base for Safety and Effectiveness of Commercially Available Endovascular Repair Technology

DUBLIN, July 06, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the start of a prospective, observational, global, multi-center, real-world, post-market study to evaluate the safety and effectiveness of the Valiant Navion™ Thoracic Stent Graft System in the treatment of thoracic aortic dissection. The first patient procedure in the DISSECT-N study was performed at Northwell Health in New York, New York by Derek Brinster, M.D., director of Aortic Surgery.

"Treatment of aortic dissection is often challenging, especially as patients with fragile aortas have different needs. The Valiant Navion CoveredSeal configuration, designed with fragile aortic tissue in mind, can be especially helpful in treating this condition," said Ross Milner, M.D., director of the Center for Aortic Diseases at the University of Chicago Medicine in Chicago and U.S. principal investigator for the DISSECT-N study. "I believe the DISSECT-N study — one of the larger prospective aortic dissection repair studies, which includes independent core-lab imaging review — will offer critical contemporary insights about TEVAR use in patients with various types of thoracic aortic dissection."

The DISSECT-N study will enroll at least 200 patients with an acute or chronic thoracic aortic dissection across approximately 45 sites in North America, Europe, and Asia Pacific. The primary endpoint is composite safety and effectiveness, including technical procedure success and freedom from major adverse events (MAEs) reported up to one month following the index procedure. Patients will be followed for three years. Primary investigators are Dr. Milner and Robin Heijmen, M.D., Ph.D., cardiothoracic surgeon at St. Antonius Hospital in the Netherlands.

"Thoracic aortic dissection is dangerous, with some cases leading to severe internal bleeding or irreversible organ damage; with the Valiant Navion system, more patients with aortic dissection are eligible for thoracic endovascular aneurysm repair (TEVAR)," said Dr. Heijmen, European principal investigator for the DISSECT-N study. "I am pleased to support the generation of real-world evidence in this landmark study, which I believe will help enable the clinical community to optimally treat patients with thoracic aortic dissection using this technology."

"There remains a significant clinical unmet need in treating thoracic dissection, and we are dedicated to improving the care for these patients through an endovascular approach," said John Farquhar, vice president and general manager of the Aortic business, which is part of the Cardiac and Vascular Group at Medtronic. "With the DISSECT-N study, we hope to further support the Valiant Navion system as a less invasive approach to treating this condition."

The low-profile Valiant Navion system received U.S. Food and Drug Administration approval in October 2018, CE Mark in November 2018, and approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan in September 2019.

An aortic dissection is a serious condition in which the inner layer of the lower aorta is torn, causing the inner and middle layers of the aorta to separate (dissect). If the blood-filled channel ruptures through the outside aortic wall, aortic dissection is often fatal.1 About two-thirds of people who have an aortic dissection are male, and those with high blood pressure or high cholesterol may be at greater risk.2

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 90,000 people worldwide, serving physicians, hospitals and patients in approximately 150 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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1 “Aortic Dissection.” *Mayo Clinic*, https://www.mayoclinic.org/diseases-conditions/aortic-dissection/symptoms-causes/syc-20369496. Accessed 10 March 2020.

2 “Your Aorta: The Pulse of Life.” *American Heart Association*, https://www.heart.org/en/health-topics/aortic-aneurysm/your-aorta-the-pulse-of-life. Accessed 10 March 2020.

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