Medtronic News

Medtronic Receives FDA Approval for Valiant Navion(TM) Thoracic Stent Graft System

GLOBE NEWSWIRE via COMTEX) --Next-Generation Thoracic Endovascular Repair (TEVAR) Device Expands Applicability to Broader Range of Patients

DUBLIN - October 23, 2018 - Medtronic plc (NYSE:MDT) today announced it has received U.S. Food and Drug Administration (FDA) approval for the Valiant Navion(TM) thoracic stent graft system for the minimally invasive repair of all lesions of the descending thoracic aorta, including thoracic aortic aneurysms (TAA), blunt thoracic aortic injuries (BTAI), penetrating atherosclerotic ulcers (PAU), intramural hematomas (IMH), and aortic type B dissections (TBAD).

Until now, patients with small iliac arteries were considered ineligible for thoracic endovascular aneurysm repair (TEVAR) or required adjunctive procedures to accommodate calcification and tortuosity concerns. Valiant Navion allows for the potential for more patients to receive a percutaneous procedure and overcome these anatomical concerns, enabling a less invasive approach to treatment compared to surgical cut-down (open) procedures.

"Our focus at Medtronic continues to be on advancing the treatment of complex aortic disease to improve outcomes and extend life," said John Farquhar, vice president and general manager of the Aortic business, which is part of the Cardiac and Vascular Group at Medtronic. "This FDA approval now makes it possible for more patients with thoracic aortic disease to receive endovascular repair. This therapy is truly a testament to our more than 20 years of clinical and engineering insights, and we look forward to making it available to those in need."

The Valiant Navion system is a lower-profile evolution of the market-leading Valiant(TM) Captivia(TM) thoracic stent graft system, which has treated more than 100,000 patients globally. Valiant Navion is built on the design philosophy of the Valiant Captivia system for improved performance and increased patient applicability. The system also features both CoveredSeal (proximal covered) and FreeFlo (proximal bare metal) stent configurations, providing physicians with two graft options to treat varying patient anatomies and pathologies.

"A significant reduction of the delivery system profile enables physicians to better facilitate the endovascular treatment of patients with smaller, tortuous, and calcified access vessel arteries," said Ali Azizzadeh, M.D., the U.S. principal investigator for the Valiant Navion IDE study. "Furthermore, the challenging anatomical and comorbid baseline characteristics and resulting clinical evidence of the global investigational device exemption (IDE) subjects support this design."

Approval was based on 30-day primary endpoint analysis of 87 subjects consecutively enrolled in the international, multicenter, prospective investigational device exemption (IDE) study analyzing the safety and efficacy of Valiant Navion in subjects with TAA and PAU. The study included a challenging real-world patient population with 37.9 percent female enrollment and 71.3 percent subjects with severe to life-threatening systemic disease (ASA physical status classification III/IV). The results demonstrated efficacy, with:

- FreeFlo configuration implanted in 74.7 percent of procedures with no instances of access or deployment failures at implant in the full study cohort.

- The new CoveredSeal proximal configuration implanted in 25.3 percent of procedures with no instances of access or deployment failures at implant in the full study cohort.

The majority of procedures (50.6 percent) were performed through a percutaneous access approach, leading to operational efficiency with mean procedure and fluoroscopy times of 88.7 ± 53.4 minutes and 12.2 ± 8.8 minutes, respectively.

Through 30 days, data showed low rates of peri-operative mortality at 2.3 percent (2/87) and secondary procedures at 2.3 percent (2/87). The rate of Type Ia endoleaks was 1.2 percent (1/87) at one-month imaging follow-up.

Approximately six out of 100,000 people globally experience a thoracic aortic aneurysm (TAA), a blood-filled bulge or ballooning of the aorta that runs through the chest and can lead to a life-threatening rupture and hemorrhage if not treated. Most people with TAA do not have any symptoms; however, risk factors include smoking, obesity, heredity, injury, or other disease.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 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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