Medtronic News

Medtronic Announces Shonin Approval and Launch of the Valiant Navion™ Thoracic Stent Graft System in Japan

Lower-Profile Thoracic Endovascular Aortic Repair (TEVAR) Device Continues to Broaden Global Treatable Patient Population with Thoracic Aortic Disease

DUBLIN, Oct. 31, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced Shonin approval from the Ministry of Health, Labour and Welfare (MHLW) and the launch of the Valiant Navion™ thoracic stent graft system in Japan for the minimally invasive repair of thoracic descending aortic aneurysms (TAA) and complicated type B aortic dissections (TBAD). The news marks the third major geographical launch of the Valiant Navion, following FDA and CE Mark approvals in late 2018.

The low-profile Valiant Navion system is built to further improve upon the performance of the market-leading Valiant™ Captivia™ thoracic stent graft system, which has treated more than 100,000 patients globally, while also broadening patient applicability. With the Valiant Navion system, physicians now have two graft options for the management of challenging thoracic aorta pathologies, including fragile aortas. The system features the CoveredSeal (proximal covered) and FreeFlo (proximal bare metal) stent configurations - both with tip capture accuracy.

Hideyuki Shimizu, M.D., Ph.D, director of the Japanese Society for Vascular Surgery, served on the team of physicians treating the first patients in Japan to undergo a procedure with the Valiant Navion system at the Keio University of Medicine, where he is also a professor of surgery and cardiovascular surgery.

“In Japan, patients experience greater aortic fragility in acute dissection compared to North America and Europe. In my experience, Valiant Navion’s 18F profile allows physicians to treat smaller and more torturous anatomy while managing patient populations with increased inflammatory states, risks of hypertension, and aortic wall stress – all attributes and conditions that are particularly relevant to the Japanese patient population,” said Dr. Shimizu. “This device allows Japanese physicians to more precisely treat a variety of patient anatomies and pathologies with narrow vessel access.”

“In just one year, the Valiant Navion system has achieved significant impact in expanding minimally invasive treatment options to patients globally,” said John Farquhar, vice president and general manager of the Aortic business, which is part of the Cardiac and Vascular Group at Medtronic. “TEVAR is not one size fits all. By designing a device with a global patient population in mind, we have ultimately broadened patient applicability and allowed for more patients to receive endovascular repair. The success of Valiant Navion is indicative of our drive and commitment to go further, together and deliver the best outcomes to the most patients.”

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 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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