Medtronic News

Medtronic Receives FDA Breakthrough Device Designation for Developing Stent Graft System to Treat Thoracoabdominal Aortic Aneurysm

News Follows Medtronic Receiving FDA Breakthrough Device Designation for its Valiant Navion™ LSA Branch Thoracic Stent Graft System

DUBLIN, Oct. 08, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its Valiant® TAAA Stent Graft System for minimally invasive repair of thoracoabdominal aortic aneurysm (TAAA). A TAAA is a complex condition causing a bulging of the aorta, which extends from the chest down into to the abdomen.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

The Valiant TAAA is currently being evaluated in the U.S. within five physician-sponsored investigational device exemption (PS-IDE) trials for treatment of TAAA. The system under evaluation in these trials was developed in collaboration with Patrick Kelly, M.D., a vascular surgeon and inventor specializing in complex vascular disease who leads Sanford Health Commercialization. The Valiant TAAA is intended to offer an off-the-shelf endovascular solution with a size matrix to enable broad patient applicability for one of vascular surgery's most difficult pathologies.

"Breakthrough designation from the FDA means that we will be able to deliver this much needed treatment to patients sooner than expected. With an open surgery mortality rate of 25%, it is critical that we deliver for this unmet patient need," said Murray Shames, M.D., professor and chief division of Vascular Surgery at the University of South Florida Morsani School of Medicine and an investigator for the Valiant TAAA. "Physicians and industry must continue to innovate and provide hope for those with challenging disease states."

TAAA typically involves the branch arteries that supply blood to multiple internal organs and represents about 15% of all thoracic aneurysms. The standard of care is complex open surgery, which is associated with high morbidity and mortality, and 40% of patients are not considered candidates for treatment.

"In addition to a high mortality rate for open surgical repair, physicians do not have good options when it comes to treatment for failed endografts," said John Farquhar, vice president and general manager of the Aortic business, which is part of the Cardiac and Vascular Group at Medtronic. "The FDA's breakthrough designation for Valiant TAAA and our collaboration with leading physicians is an example of our willingness to take a courageous approach and challenge the limitations of current treatment options. This is about going further, together to improve patient outcomes."

Continuing Expansion into Breakthrough Technologies with Valiant Navion™ LSA

The Valiant Navion™ LSA branch thoracic stent graft system received breakthrough designation from the FDA in May 2019 to allow for more timely delivery of treatment options for patients in need of left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR).

Valiant Navion LSA is based on Valiant Mona LSA investigational device and the FDA-approved Medtronic Valiant Navion stent graft system. Like Valiant Navion, the off-the-shelf, single branch device leverages a low-profile design, which may further enable patient applicability and access. The branch cuff is intended to replicate the natural anatomy of the LSA to maximize seal and patency.

“About 40% of thoracic aortic aneurysms in branch vessels involve coverage of the LSA. With no currently available off-the-shelf solutions, surgical bypass remains the standard of care for these patients,” added Farquhar. “By leveraging our low-profile, Valiant Navion platform, we hope Valiant Navion LSA will expand endovascular treatment options to those in need. It is a matter of putting patients first and delivering innovation where it matters most.”

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 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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