Medtronic News

Medtronic Expands Heart Valve Portfolio with FDA Approval and CE Mark of the Avalus(TM) Surgical Aortic Valve

Introduction of New Pericardial Aortic Heart Valve in the U.S. and Europe Reinforces Company's Commitment to Comprehensive Solutions to Heart Valve Disease

DUBLIN - August 2, 2017 - Medtronic plc (NYSE: MDT) today announced CE*(Conformité Européenne)* mark and U.S. Food and Drug Administration (FDA) approval of its new Avalus(TM) pericardial aortic surgical valve for the treatment of aortic valve disease. The Avalus valve leverages proven surgical bioprosthetic valve concepts with added features designed to enhance clinical performance, helping to address the contemporary needs of cardiac surgeons, as well as patients who are candidates for aortic valve replacement. The Avalus valve is the latest addition to Medtronic's robust portfolio of innovative heart valve therapy solutions. In addition to being the only stented surgical aortic valve on the market that is MRI-safe (without restrictions), the Avalus valve is designed for excellent implantability, an important factor during complex cases.

"The proven design elements of the Avalus valve were selected with physicians and patients in mind striving to improve upon the latest generation of stented tissue valves while maintaining the gold standard in cardiac surgery," said Robert Klautz, M.D., cardiac surgeon and department head of cardiothoracic surgery at the Leiden University Medical Center in The Netherlands. Prof. Klautz is also the co-primary investigator of the PERIGON trial, evaluating the safety and efficacy of the Avalus valve. "Based on my early clinical experience, the unique design elements of the Avalus valve position it well toward meeting the expectations of durability for new tissue valves and helps ease implantation in a wide range of patient anatomies."

The Avalus valve represents the next generation in pericardial aortic surgical valves for patients who are candidates for surgery. The Avalus valve features several significant developments, including:

- a supra-annular design for excellent hemodynamic performance, intended to limit central regurgitation.
- Interior-mounted leaflet and frame design to enhance durability.
- a low-profile valve design, streamlined valve holder and a single, one-cut release to facilitate ease of implantation.

"Medtronic is committed to advancing its surgical portfolio to offer cardiac surgeons a contemporary option to help meet the individual needs of this patient population," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "By continuing to collaborate with leading cardiac surgeons around the world, we look forward to bringing heart valve replacement solutions like the Avalus valve to assist in expanding access and improving outcomes for clinical and patient communities."

The CE Mark and FDA approval of the Avalus valve is based on subsets of data from the PERIGON Pivotal Trial, a single arm, non-randomized, prospective study of more than 1,100 patients from approximately 40 clinical sites across Europe, Canada and the United States. One of the largest, most comprehensive and modern data sets of surgical aortic valve replacement (SAVR) patients, results from the trial were recently presented by Dr. Joseph Sabik of the UH Cleveland Medical Center at the American Association of Thoracic Surgery (AATS) annual meeting in Boston, and showed low rates of adverse valve-related events, high survival and improved hemodynamic performance at one year. Patients enrolled in the trial will be followed out to five years. The Avalus valve will be commercially available later this year.

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 91,000 people worldwide, serving physicians, hospitals and patients in more than 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.

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