Medtronic News

Medtronic Announces Reimbursement Approval and Launch of CoreValve(TM) Evolut(TM) R System in Japan

Medtronic Introduces First-and-Only Recapturable TAVI System Available in Japan

DUBLIN - Dec. 1, 2016 - Medtronic plc (NYSE: MDT) today announced it has received reimbursement approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for the recapturable, self-expanding transcatheter CoreValve(TM) Evolut(TM) R System for patients with severe aortic stenosis (AS) unable to undergo surgery, and for whom treatment with transcatheter aortic valve implantation (TAVI) is determined to be the best option. This approval follows the Shonin approval from the MHLW the company received in November. The approval is based on robust data from the CoreValve U.S. Pivotal and CE Mark Clinical Trials, which demonstrated high rates of survival, low rates of stroke and excellent hemodynamics.

Designed to treat patients with aortic stenosis, a condition where the aortic valve narrows thereby limiting blood flow from the aorta to the rest of the body, the CoreValve Evolut R System is built on the proven foundation and procedural success of the CoreValve System, which has been implanted in more than 120,000 patients in 60 countries.

"TAVI continues to grow as an established treatment for inoperable AS patients in Japan and we are excited to have a next-generation, self-expanding option, as the Evolut-R system has demonstrated exceptional clinical results in studies globally," said Yoshiki Sawa, M.D., professor in the Department of Cardiovascular Surgery at Osaka University Graduate School of Medicine in Osaka, Japan. "Clinical data show the advancement of recapturability with Evolut R gives physicians more confidence during the procedure, providing different advantages not currently available in other TAVI systems."

The new system consists of the CoreValve Evolut R transcatheter valve and the EnVeo(TM) R Delivery System, which features an Enveo R InLine(TM) Sheath that significantly reduces the profile to the lowest on the market (14 Fr equivalent, less than 1/5 inch). The Evolut R System, with its self-expanding nitinol frame, is designed to optimally fit within the native aortic valve, using its supra-annular valve position to help achieve excellent hemodynamic performance.

"Heart teams made up of cardiac surgeons and interventional cardiologists in Japan are making important TAVI treatment decisions for patients who may benefit from this less invasive valve replacement procedure, and now having the option to recapturable and reposition will only help to improve patient outcomes," added Shigeru Saito, M.D., director of cardiology and catheterization laboratories at Shonan Kamakura General Hospital in Kamakura, Japan.

Based on the knowledge gained through extensive experience with the CoreValve System, the Evolut R is intended to increase conformability and sealing at the annulus. An extended sealing skirt on the 26mm and 29mm valve sizes is intended to further promote valve sealing at the annulus.

"This approval stems from our global commitment to building a market-leading innovation pipeline in the transcatheter space, and we look forward to supporting Japanese heart teams as they look to next-generation technologies to improve valve performance for a broad range of patients," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, which is part of the Cardiac and Vascular Group at Medtronic. "We look forward to introducing this next-generation, recapturable technology to indicated patients in Japan."

The CoreValve System was the first self-expanding TAVI system to be approved in Japan in March of 2015.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 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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