Medtronic News

Medtronic Announces CE Mark and European Launch of Recaptureable TAVI System Now Available for Severe Aortic Stenosis Patients with Large Anatomies

Larger Device Offers Treatment to Patients Without a Previous TAVI Option

DUBLIN - Jan. 17, 2017 - Medtronic plc (NYSE:MDT) today announced the CE (Conformité Européenne) mark and European launch of the CoreValve(TM) Evolut(TM) R 34 mm valve-the largest sized transcatheter aortic valve implantation (TAVI) system available in Europe. The new Evolut R 34 mm valve is approved for severe aortic stenosis patients who are at intermediate, high or extreme risk for surgery with an annulus size ranging from 26-30 mm. This large valve segment is estimated to account for approximately 20-25 percent of the eligible European TAVI patient population. Previously, some of these patients were unable to receive a TAVI due to the larger size of their native diseased aortic valve.

"It's important that patients with large aortic root anatomies can also have access to this recapturable TAVI system, which has proven to be an excellent treatment option for many patients," said Darren Mylotte, M.D., interventional cardiologist at the University Hospitals and National University of Ireland in Galway, Ireland. "Consistent with the Evolut R platform, the 34 mm valve delivery system assists with accurate placement with the option to recapture and reposition if needed; this gives physicians great confidence that exceptional outcomes can be achieved for our patients."

The Evolut R 34mm valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine Sheath. The system delivers the lowest, true delivery profile currently on the market (16 Fr equivalent, approximately 1/5 inch or 1/2 cm), which provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route. The Evolut R System, with its self-expanding nitinol frame, is designed to fit within the native aortic valve, using its supra-annular valve position to help achieve excellent hemodynamic performance.

"We look forward to working with physicians across Europe to offer this highly anticipated valve size to the thousands of patients who were previously unable to receive TAVI due to valve size," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "With this approval, the Evolut R platform now treats the broadest annulus range of any TAVI system on the market and expands the patient population that can now receive this life-saving therapy."

The CoreValve Evolut R 34 mm valve received Food and Drug Administration (FDA) approval in the United States in October 2016 for severe aortic stenosis patients who are at high or extreme risk for surgery with an annulus size ranging from 26-30 mm.

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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