Medtronic News

Medtronic Announces CE Mark and European Launch of CoreValve(TM) Evolut(TM) PRO Transcatheter Valve with Advanced Sealing

DUBLIN - July 31, 2017 - Medtronic plc (NYSE:MDT) today announced CE (Conformité Européenne) mark and European launch of the CoreValve(TM)Evolut(TM) PRO valve for the treatment of severe aortic stenosis for symptomatic patients who are at intermediate, high or extreme risk for open heart surgery. Clinical data for the Evolut PRO valve was recently unveiled at the American College of Cardiology (ACC) 66th Annual Scientific Session, and showed high survival, low rates of stroke, minimal paravalvular leak (PVL) and excellent hemodynamics.

The Evolut PRO device features a unique valve design with an outer wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing performance. The biocompatible porcine pericardial tissue wrap, in addition to other design elements, is incorporated to address the occurrence of blood leaking through the sides of the valve.

"The Evolut PRO valve has shown impressive clinical outcomes, with low paravalvular leak and pacemaker rates," said Nicolas M. Van Mieghem, MD, director of interventional cardiology at Erasmus Medical Center in Rotterdam, The Netherlands. "With its ease-of-use and deliverability, the Evolut PRO valve will bring TAVI practice to a higher level, and I look forward to seeing it utilized in patients across Europe."

The Evolut PRO Clinical Study (N=60) met its primary endpoint at 30 days with high rates of survival (98.3 percent) and low rates of disabling stroke (1.7 percent). The Evolut PRO valve also showed strong hemodynamic performance with large aortic valve areas (2.0 ± 0.5 cm2) and mean gradients in the single digits (6.4 ± 2.1 mm Hg) at 30 days. The majority of study subjects (72.4 percent) experienced no/trace PVL and no incidents of moderate or severe PVL were observed at 30 days. Additionally, improving on the already low rates seen in Evolut R clinical studies and real-world TVT and FORWARD registries, the rate of new pacemaker implantation was 10 percent.

Built on the proven platform of the recapturable CoreValve Evolut R System, the Evolut PRO valve includes a self-expanding nitinol frame with its supra-annular valve position that helps achieve excellent hemodynamic performance.

"We are excited to introduce the next evolution of our Evolut TAVI platform to provide physicians in Europe with a comprehensive portfolio to address their patients' needs," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group.

The Evolut PRO System is delivered through the EnVeo(TM) R Delivery Catheter System and is indicated for vessels down to 5.5 mm. The EnVeo R system features an InLine Sheath that makes it the lowest delivery platform currently on the market. It also provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route.

The 23 mm, 26 mm and 29 mm sizes of the Evolut PRO System received FDA approval in March 2017 and are available for use in the United States.

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 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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