Medtronic News

Medtronic Receives FDA Approval for CoreValve(TM) Evolut(TM) Pro Transcatheter Valve with Advanced Sealing

First-Ever Data at ACC.17 Confirms Safety and Efficacy of New Self-Expanding, Recapturable Heart Valve at 30-Days with High Survival, Low Stroke and Minimal Paravalvular Leak

DUBLIN - March 22, 2017 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval and U.S. launch of the CoreValve(TM) Evolut(TM) PRO valve for the treatment of severe aortic stenosis for symptomatic patients who are at high or extreme risk for open heart surgery. The approval comes on the heels of new 30-day clinical data that was unveiled at the American College of Cardiology (ACC) 66th Annual Scientific Session, which showed high survival, low rates of stroke, minimal paravalvular leak (PVL) and excellent hemodynamics for the self-expanding valve.

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.

"Based on my experience implanting the Evolut PRO valve during the clinical study, I've been impressed by the clinical outcomes achieved in our patients," said Mathew Williams, M.D., chief of Adult Cardiac Surgery and director of Interventional Cardiology and the Heart Valve Program at the NYU Langone Medical Center in New York City. "This innovation represents an important advantage over previous generations of this device, as it can help assist with adequate sealing even in complex cases."

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.

"The 30-day clinical outcomes presented at ACC demonstrate the Evolut PRO valve to be an outstanding treatment option for patients with severe aortic stenosis who are at a high or extreme risk for surgery," said John Forrest, M.D., assistant professor of medicine at Yale University School of Medicine in New Haven, Conn., who presented the data at the meeting.

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.

"Medtronic remains committed to working with interventional cardiologists and cardiac surgeons to deliver solutions that address patient needs with the safety and performance profile they expect from Medtronic," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "We are excited to introduce the next evolution of our Evolut TAVR platform to provide physicians with a comprehensive portfolio to address their patients' needs."

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 are available for use in the United States. It is not available for

use in countries outside of 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 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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