Medtronic News

Medtronic Announces Clinical Study to Evaluate the CoreValve(TM) Evolut(TM) PRO System in 'Everyday' Clinical Practice

New Study Designed to Assess Longer-Term Clinical Performance of Next-Generation Evolut PRO Transcatheter Aortic Valve Implantation (TAVI) System

DUBLIN - September 21, 2017 - Medtronic plc (NYSE: MDT) today announced a new post-market clinical study to evaluate its CoreValve(TM) Evolut(TM) PRO valve in everyday clinical practice. Studying patients with severe symptomatic aortic stenosis at an intermediate, high or extreme risk for open heart surgery, the FORWARD PRO Clinical Study will evaluate longer-term performance (out to five years) of the next-generation self-expanding TAVI system, which was recently approved for commercial use in Europe and United States.

The Evolut PRO valve - built off the proven Evolut R platform - is uniquely designed with an outer tissue wrap 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 first-ever data for Evolut PRO valve presented at ACC.17 showed no moderate/severe paravalvular leak (0 percent), high rates of survival (98.3 percent) and a low rate of disabling stroke (1.7 percent) at 30 days.

The multi-center, prospective single-arm study will enroll 600 patients across 35 sites in Europe, and will evaluate safety including all-cause mortality and all stroke at 30 days and clinical performance including valve hemodynamics and paravalvular regurgitation. Patients will be followed out to five years.

"We look forward to replicating the excellent clinical outcomes demonstrated by the Evolut PRO valve in a study designed to look at the valve's longer-term real-world performance," said Prof. Eberhard Grube, M.D., director of the Structural Heart Program at University Hospital in Bonn, Germany, and co-principal investigator of the FORWARD PRO Study. "The Evolut PRO has shown exceptional results for patients with severe aortic stenosis and we are excited to enroll our first patients into this rigorous study."

"As new products are introduced to the global transcatheter valve market, Medtronic continues to stay focused on driving meaningful clinical outcomes that matter to patients and that resonate with physicians," said Pieter Kappetein, M.D., vice president, medical affairs for Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic. "We believe the improvements made to the self-expanding Evolut TAVI platform will continue to improve patient outcomes, and we anticipate this real-world study will demonstrate further evidence of longer-term performance and safety."

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 84,000 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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