Medtronic News

Medtronic Enrolls First Patients in Clinical Study to Evaluate the CoreValve(TM) Evolut(TM) R System in 'Real-World' Setting

FORWARD Clinical Study Designed to Confirm the Exceptional Results Achieved in the Evolut R CE Study

DUBLIN - March 7, 2016 - Medtronic plc (NYSE: MDT) today announced the first patients enrolled in the Evolut R FORWARD Clinical Study, a global, multi-center, single-arm, prospective study of up to 1,000 patients, to evaluate performance outcomes using the CoreValve(TM) Evolut(TM) R System in everyday clinical practice. A next-generation, recapturable and repositionable transcatheter aortic valve implantation (TAVI) system, Evolut R has shown the highest reported survival rate (93.3 percent) for high and extreme risk aortic stenosis patients at one-year follow-up according to data from the Evolut R CE Study that was recently presented at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Aortic stenosis is a condition where the aortic valve narrows thereby limiting blood flow from the aorta to the rest of the body.

The first patients in the study were enrolled at University Hospital in Bonn, Germany, by the team of Prof. Georg Nickenig.

The study will enroll high- and extreme-risk patients in at least 60 centers worldwide and will document the clinical and device performance outcomes of the Evolut R System used in routine clinical practice. The primary endpoint will evaluate all-cause mortality at 30 days post-implant in patients with severe symptomatic aortic valve stenosis. Secondary endpoints will include VARC-2 safety and efficacy. The study is designed to develop rigorous evidence through complete monitoring at all centers, leveraging independent safety review and core-lab adjudicated hemodynamic performance. Follow-up will be conducted at implant, 30-days, one-year, two-years and three-years post-implant.

"Evolut R has demonstrated some of the most promising clinical results of any TAVI valve in its pre-market trial, and we are excited to enroll our patients into this rigorous study to show that the same results can be delivered in a real world clinical setting," 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 Study.

Built on the proven foundation and procedural success of the CoreValve System, which has been implanted in more than 100,000 patients in 60 countries, the CoreValve Evolut R is available in Europe and other countries that recognize the CE (Conformité Européene) Mark and was approved for commercial use in the United States in 2015. Geographies participating in the study include centers in Europe, Australia, the Middle East, Africa, Latin America and Canada.

Data from the Evolut R CE Study, which evaluated high- and extreme-risk patients with aortic stenosis, reported a low, one-year stroke rate at 3.4 percent, strong hemodynamic performance (single-digit gradients at one year), low rates of moderate or severe paravalvular leak (4.3 percent at one year), and low pacemaker implantation rate (15.2 percent one year).

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 85,000 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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