Medtronic News

Medtronic Evolut(TM) PRO TAVR System with Advanced Sealing Maintains Excellent Outcomes Over Time

Evolut PRO Valve Well-Positioned for Future with New Study Unveiled to Investigate Expanded Patient Population

DUBLIN and DENVER - November 2, 2017 - Medtronic plc (NYSE:MDT) today presented new data at the Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting showcasing the excellent clinical performance of the Evolut(TM) Transcatheter Aortic Valve Replacement (TAVR) platform. Six-month data from the newest-generation Evolut PRO System demonstrated continued benefits of its unique valve design. Results from the STS/ACC TVT Registry with the Evolut R in patients with bicuspid aortic valve disease were also presented.

Evolut PRO 6-Month Outcomes

Following the exceptional early clinical outcomes at 30-days from the Evolut PRO U.S. Study, follow-up data in 60 patients continued to demonstrate low rates of paravalvular leak (PVL) as 88 percent of patients showed no or trace PVL at six months. Additionally, rates of all-cause mortality and disabling stroke were low at six months with no instances of coronary obstruction or valve thrombosis, and the permanent pacemaker implantation rate remained low at 11.7 percent.

"These latest six-month results suggest that the Evolut PRO valve, with its self-expanding nitinol frame and outer pericardial tissue wrap, maintains a very low incidence of paravalvular leak," said John Forrest, M.D., director of interventional cardiology at Yale New Haven Hospital in New Haven, Conn. "It is encouraging to observe the sustained low rates of PVL over time combined with exceptional hemodynamics, while maintaining a low rate of new pacemaker implants."

STS/ACC TVT Registry Bicuspid Data

Further strengthening the clinical evidence for the Evolut TAVR platform, separate clinical evidence was unveiled at TCT from the STS/ACC TVT Registry, which compared patients at high surgical risk with bicuspid aortic valve disease (N=191) to those with severe tricuspid aortic valve disease (N=6526) in real-world clinical practice. Patients with bicuspid aortic valve disease are unique in that they have two aortic valve leaflets instead of the more common three leaflets (tricuspid).

At 30-days, clinical outcomes were similar for the bicuspid group compared to the tricuspid group with lower rates of all-cause mortality (2.2 percent vs. 3.2 percent), stroke (2.6 percent vs. 3.4 percent) and major vascular complications (0.5 percent vs. 1.6 percent). Additionally, hemodynamic outcomes were similar between the groups with both patient populations showing a symptomatic improvement over time.

"The results from this large, real-world analysis are promising indicators for new patient populations in the future," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center, Boston, Mass. "We look forward to further study and evaluation."

To further support TAVR clinical evidence for the treatment of bicuspid patients, Medtronic announced plans to conduct a new study in a bicuspid patient population. The study will utilize the Evolut PRO TAVR system.

The CoreValve Evolut TAVR platform consists of the CoreValve, CoreValve Evolut R and the CoreValve Evolut PRO systems, all of which have received CE mark and FDA approval for use in severe aortic stenosis patients at an intermediate surgical risk or greater.

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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