Medtronic News

New Data on CoreValve(TM) and Evolut(TM) R Self-Expanding TAVI Systems Show Excellent Clinical Outcomes in Routine Clinical Practice

Late-Breaking Real-World Study Results at EuroPCR from CoreValve ADVANCE and Evolut R FORWARD Registries Show Strong Performance Consistent with Data from CoreValve Randomized Clinical Trials

DUBLIN and PARIS - May 16, 2017 - Medtronic plc (NYSE:MDT) today unveiled new positive data on the self-expanding CoreValve(TM) platform from the CoreValve ADVANCE and Evolut R FORWARD clinical studies - two large, rigorous global registries presented during Hot Line/Late-Breaking Clinical Trial Sessions at the 2017 EuroPCR Annual Meeting. Consistent with the excellent results achieved in clinical trials, the studies reinforce the exceptional safety and efficacy profile of the CoreValve(TM) System and the newer CoreValve(TM) Evolut(TM) R System for the treatment of transcatheter aortic valve implantation (TAVI) in "real-world" patient populations with severe aortic stenosis.

CoreValve ADVANCE Study

Five-year results from 465 patients in the ADVANCE Clinical Trial demonstrated sustained, longer-term performance with the CoreValve System in a "real-world" patient population. The CoreValve System demonstrated sustained hemodynamic improvement in patients available for long-term follow-up (9.7 mm Hg mean gradient at discharge; 8.8 mm Hg mean gradient at five years). Additionally, most patients continued to have symptomatic improvements with 81 percent of patients classified as NYHA (New York Heart Association) class I or class II.

In a higher-risk patient population, survival is in line with other five-year TAVI data in similar high-risk patients.

"As TAVI continues to be evaluated in lower-risk patients, the ability to demonstrate sustained valve durability over time is of increasing importance," said Axel Linke, M.D., professor of medicine at the University of Leipzig, Heart Center, Germany, and principal investigator of the ADVANCE Clinical Trial. "At final, five-year follow-up, we are very pleased with the excellent performance of the first-generation CoreValve device in the ADVANCE study, which is one of the most rigorously designed global TAVI trials to date."

Evolut R FORWARD STUDY

Clinical results from the full patient cohort (n=1,038 patients) enrolled in the Evolut R FORWARD Clinical Study demonstrated high survival (98.1 percent) and a low rate of disabling stroke (1.8 percent) at 30-days post implant. The FORWARD study is a global, single-arm, prospective study at 53 centers across four continents. Patients enrolled in the study had a mean STS Predicted Risk of Mortality estimate of 5.5 percent.

"The FORWARD results with a large patient cohort are encouraging, as these data support the clinical safety and effectiveness of the Evolut R System," said Prof. Eberhard Grube, M.D., head, Center of Innovative Interventions (CIIC) at the University Hospital Bonn, Germany, and co-principal investigator of the FORWARD Study. "These initial 30-day outcomes help to further demonstrate the advantages of the recapturable and repositionable capabilities of the Evolut R System in routine clinical practice and we look forward to conducting further follow-up that will provide insights on contemporary TAVI clinical practice."

The Evolut R FORWARD study also showed excellent hemodynamic performance in which the mean aortic valve gradient was significantly reduced from 41.7 ± 16.1 mm Hg at baseline to 8.5 ± 5.6 mm Hg at discharge. Additionally, 98.1 percent of patients experienced mild or none/trace aortic regurgitation, as well as a low rate of major vascular complications (6.5 percent). New pacemaker implantations remained low (17.5 percent) with no reports of valve thrombosis reported at 30 days.

"With the recent expansion of TAVI into new patient populations, it's critical that we collaborate with heart teams to not only demonstrate clinical improvements in real-world patient populations, but to show longer-term valve success," said Rhonda

Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "Low rates of stroke, excellent hemodynamics and high survival are consistent with the contemporary results we've seen from our self-expanding TAVI platform, which continue to improve as the technology advances."

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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