Medtronic News

New Data on Medtronic Evolut(TM) R TAVR System Show Excellent 'Real-World' Outcomes in Global Patient Population

Results from FORWARD and STS/ACC TVT Registry Demonstrate High Survival and Low Rate of All Stroke for Next-Generation TAVR Device in Everyday Clinical Practice

DUBLIN and WASHINGTON, DC - Oct. 31, 2016 - Medtronic plc (NYSE: MDT) today presented new positive data from two large registries aimed at evaluating 30-day clinical performance outcomes for the self-expanding, recapturable and repositionable CoreValve(TM) Evolut(TM) R System in "real-world" severe aortic stenosis patient populations at the Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting.

Evolut R FORWARD Study

Positive early clinical results from the first 300 patients enrolled in the FORWARD study-a global, single-arm, prospective study at 60 centers across Europe, Australia, the Middle East, Africa, Latin America and Canada-marks the first time that the self-expanding Evolut R System was evaluated in routine clinical practice on a global scale. Designed to confirm the exceptional results achieved in the Evolut R CE Study for patients with severe aortic stenosis, the FORWARD study demonstrated an exceptionally high survival (98 percent) and a low rate of all stroke (3 percent) at 30-days post-implant.

The Evolut R FORWARD study also showed improved hemodynamic performance (by mean aortic valve gradient, a measure of blood flow through the valve) from 42.5 ± 17.7 mm Hg at baseline to 8.7 ±6.9 mm Hg at discharge. Additionally, there was a low rate of major vascular complications (2.7 percent) and no reports of valve thrombosis at 30-days.

"We're encouraged by the initial 30-day outcomes of the FORWARD study, which further showcase the advantages of the recapturable and repositionable capabilities of the Evolut R System," 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. "As patient follow-up continues at one, two and three-years post-implant, we look forward to seeing how the features of the Evolut R System can address everyday clinical needs in various severe aortic stenosis patient scenarios worldwide."

STS/ACC TVT Registry Data

New data from the Society of Thoracic Surgeons and American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry also demonstrated successful real-world outcomes achieved with the Evolut R System.

In the analysis of 9,616 patients implanted with Medtronic self-expanding TAVR systems, Evolut R demonstrated high survival (96.3 percent) and low rates of all stroke (3.1 percent) at 30 days, with successful valve implantation (99 percent). Patients in this analysis also experienced improved hemodynamic performance (mean gradient: 43.7 ± 15.4 mm Hg at baseline to 8.6 ± 5.5 mm Hg at discharge) and low rates of major vascular complications (1.5 percent). Additionally, post-procedure hospital stays were a median of four days for Evolut R and the majority of patients treated with Evolut R (75.7 percent) returned home following discharge, as opposed to a nursing home or other rehabilitation facility.

"As commercial adoption of the Evolut R System increases, it's important that we work in collaboration with heart teams to offer this advanced, next-generation device that helps provide clinical improvements in 'real-world' patient populations," said Rhonda Robb, vice president and general manager of the Heart Valve

Therapies business, a part of Medtronic's Cardiac and Vascular Group. "The latest FORWARD and TVT Registry results presented today further builds upon the growing body of global evidence supporting our self-expanding TAVR systems as safe and effective treatment options."

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 System 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.

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 more than 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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Contacts:
Joey Lomicky
Public Relations
+1-762-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626
