Medtronic News

Medtronic CoreValve® Evolut® R System Demonstrates Exceptional Results at One Year

New Data Released at TCT 2015 Affirms Strong Performance of Recapturable and Repositionable Heart Valve Yielding Low Rates of Mortality and Stroke with Excellent Hemodynamics

DUBLIN and SAN FRANCISCO - October 14, 2015 - Medtronic plc (NYSE: MDT) announced new one-year data showing transcatheter aortic valve replacement (TAVR) with the CoreValve® Evolut® R System-the first and only next-generation recapturable, self-expanding valve available in the U.S.-led to exceptional clinical outcomes.

Presented at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, data from the Evolut R CE Study reported the lowest rate of all-cause mortality (6.7 percent) of any TAVR study in extreme and high risk patients to date at one-year follow-up. The one-year stroke rate was also low at 3.4 percent. The Evolut R CE Study is a prospective, single-arm, multicenter study that enrolled 60 extreme and high risk patients at six centers in Australia, New Zealand and the United Kingdom.

"These data show that, even in a high and extreme risk patient population, the exceptional procedural outcomes experienced with Evolut R were maintained through one year, which indicates that this next-generation, recapturable technology delivers on its promise to advance TAVR outcomes for patients," said Ganesh Manoharan, M.D., consultant cardiologist at the Royal Victoria Hospital in Belfast, Northern Ireland and study investigator for the Evolut R CE Study who presented the data. "The low rate of paravalvular leak and new pacemaker implantation suggest that the ability to recapture and reposition during deployment will play an important role in the evolution of TAVR technology."

In the data presented today, Evolut R showed strong hemodynamic performance, which may be attributed to the valve's supra-annular design. Mean aortic gradients (a common method for measuring the restriction of blood flow through the aortic valve) remained low in the single digits at 7.5±2.7 mm Hg at one year. With optimized valve positioning accuracy due to the device's 1:1 response and controlled deployment, rates of moderate or severe paravalvular leak remained low (3.4 percent at 30 days and 4.3 percent at one year). The permanent pacemaker implantation rate was similarly low at 30 days (11.7 percent) and at one year (15.2 percent).

These data showed no incidents of valve dysfunction, procedural death, annular rupture, coronary occlusion, valve thrombosis, embolization, or conversion to surgery. Transfemoral access was possible in all but one patient in a population that included patients with smaller vessels (down to 5.0 mm).

"With the recapturable and repositionable capabilities of Evolut R, and enhancements to both the delivery system and valve design, we set out to enhance the key procedural outcomes that drive TAVR outcomes. These exceptional results clearly demonstrate that we have achieved our goal," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, which is part of the Cardiac and Vascular Group at Medtronic. "The Evolut R System represents the TAVR platform of the future. Heart teams worldwide recognize that the clinical results from this trial are exceptional, and they are excited to have next-generation technology that enables them to achieve these same positive outcomes for their own patients in their own practices."

The Evolut R valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine(TM) Sheath that significantly reduces the profile to the lowest on the market (14 Fr equivalent, less than 1/5 inch). A smaller profile size provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route, and may minimize the risk of major vascular complications in some patients.

The 23 mm, 26 mm and 29 mm sizes of the CoreValve Evolut R transcatheter valve and the CoreValve EnVeo R Delivery

Catheter System are available in Europe and other countries that recognize the CE mark. The CoreValve Evolut R System was FDA-approved for commercial use in the United States in June 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 85,000 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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