

Medtronic CoreValve(TM) Evolut R(TM) System Shows Exceptional Clinical Outcomes at One Year

New Data from Evolut R U.S. IDE study presented at TCT Reveals Positive Clinical Performance for the Recapturable TAVR Device, Including the First-of-its-Kind 34 mm Valve

DUBLIN and WASHINGTON, D.C. - Nov. 1, 2016 - Medtronic plc (NYSE: MDT) unveiled new clinical data showing that patients treated with the self-expanding CoreValve(TM) Evolut(TM) R System continued to experience excellent clinical outcomes at one year. As the first-and-only recapturable transcatheter aortic valve replacement (TAVR) technology commercially available in the United States, the Evolut R TAVR system demonstrated high rates of survival, low rates of stroke and excellent hemodynamics in the Evolut R U.S. Investigational Device Exemption (IDE) Study.

Presented at the Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting, data from the study showed that 241 patients deemed extreme and high risk with symptomatic severe aortic stenosis had high rates of survival (91.4 percent) and low rates of disabling stroke (5.1 percent) at one year. Additionally, initial use of the larger, first-of-its-kind Evolut R 34 mm valve resulted in no deaths, no strokes, no vascular complications and two pacemaker implants (13.3 percent) at 30 days.

The Evolut R 23 mm, 26 mm and 29 mm valves and the CoreValve EnVeo(TM) R Delivery Catheter System are available in the United States, as well as Europe and other countries that recognize the CE (*Conformité Européenne*) mark. The Evolut R 34 mm valve size is currently available in the United States, and limited to investigational use only outside of the U.S.

"The remarkable one-year results from the Evolut R IDE study, as well as the first outcomes with the 34 mm valve size, further strengthens the positive body of evidence that supports the Evolut R system's clinical performance in a wide range of patient anatomies," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center, Boston and presenter of the data at TCT. "It is reassuring to see that patients continued to experience positive clinical outcomes with the Evolut R system at one-year follow-up."

Excellent hemodynamic performance was also observed with mean aortic gradients (a common method for measuring the restriction of blood flow through the aortic valve) in the single digits (9.0 ± 4.8 mm Hg) at one year. There were no patients with severe paravalvular leak (PVL) and low rates of moderate PVL (3.7 percent, $n=188$). Importantly, no incidents of embolization or migration, valve dysfunction requiring repeat procedure, endocarditis or valve thrombosis were observed, and the pacemaker rate was 18.3 percent at one year.

In the Evolut R 34 mm treated group, strong hemodynamic performance at 30 days included a mean aortic valve area (EOA) of 2.8 ± 0.9 cm², mean gradient of 5.4 ± 2.3 mm Hg, and one patient with moderate PVL. No severe PVL was observed at 30 days.

"One-year data from the Evolut R U.S. IDE study reinforce the positive results from the Evolut R CE Study, demonstrating the unique ability of the Evolut R system design to assist with valve placement accuracy and improve clinical outcomes," 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. "It's especially encouraging to see the excellent initial outcomes from the Evolut R 34 mm subset, which has the potential to expand the TAVR market by enabling more patients with larger sized native valves to receive this first-of-its-kind treatment option."

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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