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Evolut™ TAVR procedural and design innovation enable strongly positive results for patients

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Optimize PRO study demonstrates improved procedure efficiencies and valve performance

Pooled analysis shows improvement in PVL with Evolut™ PRO TAVR system through 3 years

Medtronic plc, a global leader in healthcare technology, today announced new data for the Evolut™ Transcatheter Aortic Valve Replacement System (TAVR) at PCR London Valves 2024. This new clinical evidence brings further insights to global implanters treating patients with symptomatic severe aortic stenosis (SASS). New findings from the Optimize PRO clinical study demonstrated favorable procedural and clinical outcomes following use of an optimized care pathway and the cusp overlap technique (COT) to deploy Evolut™ valves. Additionally, a pooled analysis of Evolut™ PRO patients was shared showing improvement in rates of paravalvular leak (PVL) in TAVR patients, over time following hospital discharge.

Optimize PRO Study: Global Standardized TAVR Technique Delivers Favorable Procedural and Clinical Outcomes

Full 30-day findings from the Optimize PRO global study show utilization of the cusp overlap technique with the Evolut™ PRO and PRO+ devices led to favorable procedural and clinical outcomes. Findings of the multi-center, post-market, prospective study conducted in 50 centers globally demonstrated low rates of new 30-day permanent pacemaker implantation (6.4% with cusp overlap technique compliance) and no moderate or severe aortic regurgitation at discharge.

The Optimize PRO clinical study evaluated valve performance and procedural outcomes associated with an "optimized" pre- and post-procedural TAVR care pathway, utilizing the cusp overlap technique to deploy the Evolut™ valves. The cusp overlap technique is designed to help implanters assess and achieve the optimal implant depth to reduce interaction with the conduction system. At 30 days, the primary endpoint of all-cause mortality or all stroke was 5.1%, all-cause mortality 0.8%, disabling stroke 1.7%, and cardiovascular rehospitalization was 5.7%.

"We are encouraged by this data as it demonstrates significant positive outcomes when leveraging the cusp overlap technique with the Evolut valve," said Steven J. Yakubov, MD, MSCAI, FACC, OhioHealth Riverside Methodist Hospital and co-principal investigator. "The new results support a standardized protocol that will help support early hospital discharge and lower rates of complications for our patients, improving their quality of life."

Improvement in Paravalvular Leak Over Time with Evolut PRO Transcatheter Aortic Valve

This paired analysis assessed improvement in PVL over time post-TAVR with the Evolut™ PRO valve in patients with SSAS. The study analyzed core lab echocardiographic data from 620 patients treated with Evolut PRO from the prospective Evolut Low Risk Trial, FORWARD PRO Study, and Evolut PRO US Study. The analysis demonstrated improvements in severity of PVL - a leak that occurs when blood flows backward between the heart's natural tissue and a replacement valve - after 30 days post-hospital discharge to 3-year follow-up.

From the paired analysis of patients with available data at all follow-up visits, the PVL severity for 30 days post-hospital discharge was 60.8% none/trace, 36.0% mild, 2.9% moderate, and 0.3% severe. At 3-year follow-up, the PVL severity was 79.8% none/trace, 19.6% mild, 0.6% moderate and 0.0% severe. The occurrence of worsened PVL from discharge/30 days to 3-year follow-up was uncommon.

"This analysis expands upon previous studies and found a majority of patients classified with mild or greater PVL improved in their PVL severity at 3 years," said Nicolas Van Mieghem, MD, PhD, Thoraxcenter, Erasmus University Medical Center in Rotterdam, The Netherlands, and lead investigator "This study will help inform physicians on the treatment of this complication post-TAVR."

"With the Evolut TAVR system, we are committed to improving outcomes for patients while maintaining exceptional safety and efficiency" said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "The data presented at London Valves 2024 further establishes Medtronic and Evolut as leaders in the supporting and sharing the robust clinical evidence physicians need to make the best decisions for their patients when choosing and performing TAVR."

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com, and follow Medtronic on LinkedIn.

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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