Medtronic News

Medtronic Evolut™ TAVR system shows durable clinical outcomes and outstanding valve performance at five years in low-risk aortic stenosis patients

GALWAY, Ireland and CHICAGO, March 30, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced late-breaking data on five-year outcomes from the Evolut Low Risk Trial. Data shows, versus surgery, the Evolut™ transcatheter aortic valve replacement (TAVR) system delivers a numerically lower rate of all-cause mortality or disabling stroke at five years, strong valve performance and durable clinical outcomes. The findings were presented as late-breaking clinical science at the American College of Cardiology's Annual Scientific Session & Expo and simultaneously published in the JACC, the flagship journal of the American College of Cardiology

The Evolut Low Risk Trial was a randomized, multicenter, international study assessing the safety and efficacy of the Evolut TAVR system versus surgery in low-risk patients. These patients had a predicted 30-day mortality risk <3%, as assessed by a local heart team. 1,414 patients were randomized, with 730 receiving TAVR with either a Medtronic Evolut R, PRO, or CoreValve™ and 684 undergoing surgery.

"Results at five years support Evolut's supra-annular, self-expanding TAVR as a safe, effective, and durable alternative to surgery for patients with severe aortic stenosis, regardless of their surgical risk," said Michael J. Reardon, M.D., Allison Family Distinguished Chair of Cardiovascular Research and professor of cardiothoracic surgery at the Houston Methodist Hospital and principal investigator of the trial. "The lower mortality risk and strong valve performance is meaningful for clinicians in evaluating treatment approaches that prioritize the overall well-being of patients."

Patients with severe aortic stenosis who were treated with either Evolut TAVR or surgery showed comparable rates of all-cause mortality or disabling stroke at 5 years (Evolut TAVR [15.5%] and surgery [16.4%]; p=0.47). Additional findings at five years include:

- Numerically lower rate of cardiovascular mortality (7.2% Evolut TAVR vs. 9.3% surgery; p=0.15)
- Significantly larger effective orifice areas (EOA) and lower mean gradients in the TAVR vs. surgical arms

"At five years, Evolut has demonstrated lasting clinical outcomes comparable to surgery and a trend toward reduced cardiovascular mortality," said Kendra J. Grubb, M.D., M.H.A., M.Sc., vice president and chief medical officer of Structural Heart, which is part of the Medtronic Cardiovascular Portfolio. "These results reinforce the recently reported Evolut evidence from the SMART trial,[1] which emphasized superior hemodynamics and lower rates of valve dysfunction. The Evolut Low Risk data presented today will help clinicians make personalized treatment decisions for younger, lower-risk patients by considering each patient's unique needs, now acknowledging that data supports TAVR with Evolut as a safe and durable alternative to surgery."

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 (NYSE: MDT), 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.

Contact:

Kimberly Powell
Public Relations
+1-202-498-2601

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

[1]Herrmann H. Two-Year Outcomes of the Five-Year SMART Trial, presented at CRT 2025.

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