

## SMART Trial two-year data continues to demonstrate superior valve performance for Evolut TAVR™ system in small annulus patients

*CRT 2025 Late Breaking Science features largest head-to-head randomized control TAVR trial to primarily enroll women using the two most widely used global TAVR devices*

GALWAY, Ireland and WASHINGTON, March 9, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today released the two-year results of the **SM**all **A**nnuli **R**andomized **T**o Evolut or SAPIEN (SMART) Trial, the largest international head-to-head comparative trial of transfemoral transcatheter aortic valve replacement (TAVR). In patients with aortic stenosis and a small aortic annulus, results showed comparable composite outcome of mortality, disabling stroke, and heart failure hospitalization, and continued superior valve performance as measured by bioprosthetic valve dysfunction (BVD) at two years for Evolut™ TAVR compared to SAPIEN™. The late-breaking science was presented at the Cardiovascular Research Technologies (CRT) 2025 conference in Washington, D.C.

"Valve performance is critical for all patients, but the impact of poor valve performance is magnified in patients with a small aortic annulus, who are at risk of receiving a valve that is not adequate for their cardiac requirements," said Howard C. Herrmann, M.D., Perelman School of Medicine at the University of Pennsylvania, and lead investigator of the trial. "The two-year results highlight the continued superior performance of the Evolut TAVR valve in these patients. While we would not yet expect to see a significant difference in the composite clinical outcomes at this early stage, valve performance provides important data that operators can use to inform and personalize treatment decisions to enhance patient outcomes."

The SMART two-year data demonstrated that Evolut TAVR continues to show significantly less BVD, which can be a predictor of adverse outcomes<sup>1</sup>, compared to SAPIEN TAVR. Additional results demonstrated that Evolut TAVR showed the following relative to SAPIEN TAVR:

- Five times less prosthetic valve thrombosis (p=0.0048)
- Nine times less hemodynamic structural valve dysfunction (defined by mean gradient  $\geq 20$ mmHg; p<0.001)

These results build on additional data of Evolut BVD performance in small and large annulus patients, which will be presented as a late-breaker at CRT today, and the Evolut BVD pooled analysis by Dr. Steven Yakobuv published in the [Journal of the American College of Cardiology](#).

The SMART Trial is an international, prospective, multi-center, randomized (1:1) post-market trial comparing the safety and performance of Evolut self-expanding TAVR versus SAPIEN balloon-expandable TAVR in patients with symptomatic severe aortic stenosis (AS) and small aortic annulus. The trial, the largest head to head randomized control trial to primarily enroll women, randomized and treated 716 patients, 87% of which were women, across more than 80 sites worldwide.<sup>2</sup> Eligible patients had an aortic valve annulus area of  $\leq 430$  mm<sup>2</sup> as measured by computed tomography, and suitable anatomy for transfemoral TAVR with both an Evolut PRO/PRO+/FX or a SAPIEN 3™/3 Ultra™ valve. Patients enrolled in the trial will continue to be followed out to five years.

"The SMART Trial is a groundbreaking, head-to-head comparison that, for the first time, highlights how a patient with a small annulus can benefit from Evolut's differentiated valve design," said Kendra J. Grubb, M.D., M.H.A., M.Sc., vice president and chief medical officer, Structural Heart, which is part of the Cardiovascular Portfolio at Medtronic. "At two years, we continue to see superior valve performance that we will follow to assess long-term outcomes."

## About Aortic Stenosis

Aortic stenosis (AS), a narrowing of the aortic valve, is among the most common of all valvular heart diseases, impacting 1.5 million in the U.S.<sup>3</sup> Symptomatic severe AS can be fatal if left untreated and the average patient survival is two years without treatment.<sup>4</sup> Approximately 40% of the total global market is believed to have a small aortic annulus, requiring tailored valve selection for their unique anatomy.

## 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](http://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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<sup>1</sup>Généreux, P. et al. J Am Coll Cardiol. 2021;77(21):2717-46

<sup>2</sup>Herrmann HC, Mehran R, Blackman DJ, Bailey S, Mollmann H, et al. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med*. 2024 Jun 6;390(21):1959-1971.

<sup>3</sup>Carabello BA, Paulus WJ. Aortic stenosis. *Lancet*. March 14, 2009;373(9667):956-966.

<sup>4</sup>Lester SJ, Heilbron B, Gin K, Dodek A, Jue J. The natural history and rate of progression of aortic stenosis *Chest*. April 1998;113(4):1109-1114.

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