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SMART Trial three-year data demonstrate superior benefits with Evolut™ TAVR system

EuroPCR Hot Line Science features positive outcomes from the largest international head-to-head comparative trial of TAVR

Medtronic, a global leader in healthcare technology, today released the three-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 transcatheter aortic valve replacement (TAVR). In patients with aortic stenosis (AS) and a small aortic annulus, results showed all individual and composite hemodynamic measures continue to be superior at three years for Evolut™ TAVR compared to SAPIEN™. The science was presented today at EuroPCR 2026 in Paris, France.

"The continued superior hemodynamic outcomes demonstrated at three years provide important evidence of Evolut TAVR's advantage in treating patients with aortic stenosis and a small aortic annulus," said Howard C. Herrmann, M.D., lead investigator of the trial. "Additionally, these findings deliver new insights, including lower rates of valve thrombosis with Evolut. Clinical valve thrombosis is a serious complication that can drive rising gradients, valve dysfunction, and heart failure symptoms, often necessitating anticoagulation or repeat intervention, with added bleeding risk and long-term management burden."[1] "It is encouraging to see durable differences in hemodynamic performance through three years, with continued follow-up planned through 5 years," Herrmann continued.

The SMART three-year data demonstrated that Evolut TAVR provides strong outcomes compared to SAPIEN TAVR.

- Significantly lower bioprosthetic valve dysfunction (BVD) (16.3% vs 54.4%, P<0.001)
- Thrombosis rate continues to be higher with SAPIEN (Kaplan-Meier rates VARC-2: 5.8% vs 1.3%, P=0.002, VARC-3: 6.8% vs 1.3%, P<0.001)
- In an exploratory analysis, patients with ≥ moderate prosthesis-patient mismatch (PPM) experienced 2.24x cardiovascular mortality risk in SMART Trial through 3 years (p = 0.014). Moderate or greater PPM outcomes at 30 days as defined by VARC-3 were: (9.9% Evolut vs. 33.2% SAPIEN, p<0.001)
- Similar safety profile for the clinical outcome composite of death, disabling stroke, or heart failure rehospitalization through 3 years of follow-up—supporting the long-term durability and risk-benefit profile while reinforcing confidence in sustained patient outcomes.

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 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.[2] Eligible patients had an aortic valve annulus area of ≤430 mm^2 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.

"Outcomes from the SMART Trial continue to build on the clinical evidence supporting the safety and performance of Evolut TAVR," 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. "These latest findings further suggest the potential for improved long-term outcomes for patients with small aortic valve annuli, including women, and reinforce the role of Evolut TAVR in enabling more individualized treatment approaches that may help inform the future of valve care."

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.[3] Symptomatic severe AS can be fatal if left untreated and the average patient survival is two years without treatment.[4] Approximately 40% of the total global market[5] 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 90,000+ passionate people across more than 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.

[1]Généreux P, Cohen DJ, Mack M, et al. Incidence, predictors, and prognostic impact of late bleeding complications after transcatheter aortic valve replacement. *J Am Coll Cardiol.* 2014;64(24):2605-2615. doi:10.1016/j.jacc.2014.08.052.

[3]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.

[3]Carabello BA, Paulus WJ. Aortic stenosis. *Lancet.* March 14, 2009;373(9667):956-966.

[4]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.

[5]Makkar RR et al. Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study. Lancet. 2023 Oct 28;402(10412):1529-1540. doi: 10.1016/S0140-6736(23)01636-7. Epub 2023 Aug 31. PMID: 37660719.

Contact:
Ingrid Goldberg
Investor Relations
+1-763-505-2696

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

SOURCE Medtronic plc

Disclaimer: BVD is defined as a composite including any of the following:

hemodynamic structural valve dysfunction (mean gradient ≥ 20 mmHg), non-structural valve dysfunction (severe prothesis-patient mismatch or ≥ moderate aortic regurgitation), clinical thrombosis, endocarditis, and aortic valve reintervention.

https://news.medtronic.com/SMART-Trial-three-year-data-demonstrate-superior-benefits-with-Evolut-TAVR-TM-system