

SMART trial one-year data demonstrates Medtronic Evolut™ TAVR platform as optimal treatment for severe aortic stenosis in patients with small annulus, which is primarily women

New data from largest head-to-head randomized control TAVR trial demonstrates non-inferior clinical outcomes and superior valve performance for Evolut TAVR compared to Sapien™ at one year

DUBLIN and ATLANTA, April 7, 2024 /[PRNewswire](#)/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced new data from the largest head-to-head comparative trial of transfemoral transcatheter aortic valve replacement (TAVR), were presented as a late breaking clinical trial at the American College of Cardiology Annual Scientific Session and [simultaneously published](#) in *The New England Journal of Medicine*. The one-year results of the **SM**all **A**nnuli **R**andomized **T**o Evolut or SAPIEN (SMART) Trial in individuals with aortic stenosis (AS) with small aortic annuli (SAA) demonstrated noninferior clinical outcomes and superior valve performance as measured by bioprosthetic valve dysfunction performance for the Evolut™ TAVR platform compared to the SAPIEN™ platform.

"SMART was launched to better understand how the two most commonly used TAVR systems perform in patients with small aortic annuli, and particularly in women who tend to have smaller heart valves," said Nina Goodheart, senior vice president and president, Structural Heart & Aortic, which is part of the Cardiovascular Portfolio at Medtronic. "We continue to develop evidence to better understand the benefits of our Evolut TAVR technology in all patients, including patient populations that are underrepresented, under-diagnosed and under-treated. The results from the SMART trial demonstrate these benefits in a large patient population and reinforce our commitment to driving health equity and engineering the best technology to solve unmet patient needs."

In addition to being the largest comparative trial of TAVR, SMART is also the largest TAVR trial to date to enroll primarily women (87%). Symptomatic severe aortic stenosis can be fatal if left untreated and the average patient survival is two years without treatment.¹ Despite women's longer life expectancy, once impacted by severe aortic stenosis they suffer from higher mortality than men, even after matching for age.² Both TAVR and surgical aortic valve replacement (SAVR) are options for women to treat AS. Due to their smaller aortic annuli, women can often receive a valve replacement that does not properly fit their anatomy — highlighting the need for clinical evidence to inform the best treatment approaches.³ Additionally, despite prevalence of chronic conditions associated with AS in women over 65, [a new survey of over 1,000 women announced today](#) found that the majority have never been referred to a cardiologist.

"As clinicians, we know that tailored approaches are needed to address the unique presentation of AS in the small annulus patient population, which is primarily women. Little comparative data exists to help us with valve selection," said Howard C. Herrmann, M.D., Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Penn., and lead investigator of the SMART Trial. "While we know women have a greater benefit than men when treated with TAVR vs SAVR, now for the first time there is definitive data demonstrating that women have the best valve performance when treated with the Evolut TAVR system."

The SMART Trial is an international, prospective, multi-center, randomized (1:1) post-market trial comparing the safety and performance of self-expanding versus balloon-expandable TAVR in patients with symptomatic severe AS and SAA. The trial randomized and treated 716 patients, 87% of which were women, across more than 80 sites worldwide. Eligible patients had a computed tomography aortic valve annulus area of $\leq 430 \text{ mm}^2$ and

suitable anatomy for transfemoral TAVR with both an Evolut PRO/PRO+/FX or a SAPIEN 3™/3 Ultra™ valve.

"For patients with heart valve replacements, early bioprosthetic valve dysfunction can lead to increased risk of serious long term outcomes including mortality and rehospitalization," added Dr. Herrmann. "As clinicians, these data further reinforces that not all valves are the same, and we strongly need to consider valve performance when determining device selection."

Results demonstrated that the Evolut TAVR platform met both co-primary endpoints of clinical non-inferiority and hemodynamic superiority at one year.

- Evolut TAVR met non-inferiority for the clinical outcome primary endpoint, a composite of all-cause mortality, disabling stroke, or heart failure rehospitalization at one year (9.4% Evolut vs. 10.6% SAPIEN, $p < 0.001$ for non-inferiority).
- Evolut TAVR demonstrated superiority for the valve function primary endpoint, bioprosthetic valve dysfunction through one year (9.4% Evolut vs. 41.6% SAPIEN, $p < 0.001$ for superiority).

"Medtronic is committed to providing clinicians and patients with aortic stenosis long-term data to help to inform their treatment decisions," said Jeffrey Popma, M.D., vice president and Chief Medical Officer for the Coronary & Renal Denervation business and the Structural Heart & Aortic business at Medtronic. "Our prior studies have shown an important link between valve performance, mortality, and re-hospitalization at five years. All SMART patients will be followed for five years to assess the relationship between better valve performance and improved clinical outcomes in patients with small annuli."

Analyst and Investor Briefing

Medtronic will host an analyst and investor briefing to discuss the results from the SMART Trial on Sunday, April 7, 2024, at 10:45 AM EDT. The briefing will feature remarks from Medtronic management, immediately followed by answering questions from institutional investors and equity analysts. A live, listen-only webcast will be available and can be accessed by clicking on the Events link at investorrelations.medtronic.com on April 7. An archived replay will be available on the same webpage later in the day. This event is not part of the official ACC Scientific Sessions.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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.

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¹Carabello BA, Paulus WJ. Aortic stenosis. Lancet. March 14, 2009;373(9667):956-966.

²Am Heart Assoc. 2021;10:e018816. DOI: 10.1161/JAHA.120.018816.

³Lester 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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