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New data for Medtronic CoreValve/Evolut TAVR™ Systems reinforces excellent valve performance

New York Valves 2024: Late-breaking data included a SMART Trial secondary analysis showing significantly less bioprosthetic valve dysfunction with Evolut TAV across the entire range of small annulus areas when compared with the Edwards Sapien 3™ TAV platform, and CoreValve-Evolut pooled analysis demonstrating valve performance and durability benefits versus surgery.

Medtronic today announced new data from the CoreValve™ Evolut™ Clinical Program, reinforcing the positive performance of the Evolut transcatheter aortic valve replacement (TAVR) System compared to surgical aortic valve replacement (SAVR) and other TAVR valves. Two analyses were presented as late-breaking data at the New York Valves Structural Heart Summit, including a secondary analysis of the SMall Annuli Randomized To Evolut or SAPIEN (SMART) Trial and an expanded analysis of bioprosthetic valve dysfunction (BVD) outcomes from a CoreValve-Evolut pooled analysis.

The CoreValve and next-generation Evolut TAVR systems are used in TAVR procedures for patients with symptomatic severe aortic stenosis (AS), which are less invasive and typically result in a quicker recovery time than open heart surgery.[i] The studies evaluated BVD, a key component of TAVR durability.[ii]

“The late-breaking findings presented at New York Valves build on the proven valve performance and durability legacy for the CoreValve/Evolut System. We know how important valve performance and durability are when clinicians are seeking a TAVR product that is not only safe, but also reduces the risk of rehospitalization and mortality,” said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business, which is part of the Cardiovascular portfolio at Medtronic. “We believe the intentional and innovative design of the Evolut TAV platform enables the excellent and consistent clinical evidence demonstrated in randomized clinical trials. The quality of our design and the valve performance set Evolut apart from other TAVs in the market.”

Late Breaking Clinical Science: Predictors of the Primary Outcomes from the Randomized SMART Trial

Medtronic announced results from a secondary predictor analysis of the SMART Trial co-primary outcomes, originally presented at American College of Cardiology (ACC) 2024. The findings showed across all annular sizes that patients who received an Evolut™ self-expanding (SEV) had less BVD compared those who received a SAPIEN™ balloon-expandable (BEV) through one year. Further, the SMART Trial demonstrated non-inferior clinical outcomes, including a lower composite rate of all-cause mortality, disabling stroke, or heart failure

rehospitalization (9.4% Evolut vs. 10.6% SAPIEN, p<0.001 for non-inferiority) and superior valve performance (9.4% Evolut vs. 41.6% SAPIEN, p<0.001 for superiority) in SEV compared to BEV.

In addition to being the largest comparative trial of TAVR, SMART is the largest TAVR trial to enroll primarily women (87%). Despite women's longer life expectancy, once impacted by severe AS they suffer from higher mortality than men, even after matching for age.[iii] Due to their smaller aortic annuli, women can often receive a valve replacement that does not properly fit their anatomy – highlighting the need for more clinical evidence to inform the best treatment approaches.[iv]

"In our analysis, the clearest predictor of valve performance was valve type. In addition, we demonstrated that the supraannular self-expanding valve had superior valve performance across the entire range of annular areas included in the trial," said Howard C. Herrmann, MD, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Penn., and lead investigator of the SMART Trial. "The findings from the SMART Trial further emphasize the importance of considering valve function when making clinical decisions, especially when looking at specific patient populations like women, who may require more customized approaches."

Late Breaking Clinical Science: CoreValve-Evolut Pooled Analysis of Bioprosthetic Valve Performance

Expanded results from a pooled CoreValve-Evolut analysis showed that five-year valve performance was significantly better in patients with symptomatic severe AS undergoing TAVR with the Medtronic CoreValve/Evolut TAVR system compared to surgery. The analysis showed a lower risk of BVD for both small and large annuli patients with CoreValve/Evolut TAVR compared to surgery.

This study is the first to assess the validity of clinical criteria for valve function using a modern, comprehensive definition of BVD that incorporates changes in gradient from over 5,000 patients. Previously presented at CRT23 and EuroPCR23, this pooled analysis was expanded for a more comprehensive dataset including additional valve reinterventions, valve-related deaths, and unscheduled echoes.

"This new data demonstrates that the CoreValve/Evolut platform is the first and only TAVR platform to demonstrate a performance and durability benefit over surgery at five years in randomized controlled trials," said Steven J. Yakubov, MD, MSCAI, FACC, Riverside Methodist at Ohio Health and CoreValve-Evolut clinical investigator. "This is clinically significant as poor valve performance, regardless of therapy, can result in worse patient outcomes. Further, this reinforces the importance of valve selection for patients with intermediate or greater surgical risk to potentially improve long-term outcomes."

About Medtronic

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[i] Mayo Foundation for Medical Education and Research. (2023, September 6). Transcatheter Aortic Valve Replacement (TAVR). Mayo Clinic. https://www.mayoclinic.org/tests-procedures/transcatheter-aortic-valve-replacement/about/pac-20384698#:~:text=TAVR%20is%20minimally%20invasive%2C%20which,symptoms%20of%20aortic%20valve%20stenosis.

[ii] Philippe Pibarot, Howard C. Herrmann, Changfu Wu, Rebecca T. Hahn, Catherine M. Otto, Amr E. Abbas, John Chambers, Marc R. Dweck, Jonathon A. Leipsic, Matheus Simonato, Toby Rogers, Janarthanan Sathananthan, Mayra Guerrero, Julien Ternacle, Harindra C. Wijeysundera, Lars Sondergaard, Marco Barbanti, Erwan Salaun, Philippe Généreux, Tsuyoshi Kaneko, Uri Landes, David A. Wood, G. Michael Deeb, Stephanie L. Sellers, John Lewis, Mahesh Madhavan, Linda Gillam, Michael Reardon, Sabine Bleiziffer, Patrick T. O'Gara, Josep Rodés-Cabau, Paul A. Grayburn, Patrizio Lancellotti, Vinod H. Thourani, Jeroen J. Bax, Michael J. Mack, Martin B. Leon, Standardized Definitions for Bioprosthetic Valve Dysfunction Following Aortic or Mitral Valve Replacement: JACC State-of-the-Art Review, Journal of the American College of Cardiology, Volume 80, Issue 5, 2022, Pages 545-561, ISSN 0735-1097, https://doi.org/10.1016/j.jacc.2022.06.002.

[iii] Am Heart Assoc. 2021;10:e018816. DOI: 10.1161/JAHA.120.018816.

[iv] 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.

Contacts:

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

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

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