

# Anteris Reports One-Year Patient Outcomes for DurAVR® THV

*New class, biomimetic TAVR demonstrates sustained hemodynamic performance to one-year*

**MINNEAPOLIS, United States and BRISBANE, Australia 21 March 2025: Anteris Technologies Global Corp. (Anteris® or the Company)** (NASDAQ: AVR, ASX: AVR) a global structural heart company committed to designing, developing, and commercializing cutting-edge medical devices to restore healthy heart function, today announced one-year results for patients treated with its proprietary, balloon expandable, DurAVR® Transcatheter Heart Valve (THV) System. Rishi Puri, M.D. PhD will present the data at a late breaking clinical trial session at Sydney Valves on Friday 21 March 2025, 10:30am (AEST), titled: *“Pioneering a New Class of Biomimetic TAVR with Sustained 1-Year Performance.”*

## One-year Results Highlights:

- DurAVR® THV demonstrated a favorable hemodynamic profile sustained to one-year, with an Effective Orifice Area (EOA) of  $2.1 \pm 0.2$  cm<sup>2</sup>, a Mean Pressure Gradient (MPG) of  $8.6 \pm 2.6$  mmHg and Doppler Velocity Index (DVI) of 0.58.
- At one-year, clinical safety outcomes show positive results with no valve or cardiovascular related mortality and importantly no prosthesis-patient mismatch (PPM\*) reported in these small annuli patients (aortic annulus area  $395.80 \pm 37.26$ mm<sup>2</sup>).

Current commercial devices have demonstrated rates between 11.2% to 35.3% PPM<sup>1</sup>, a predictor of valve failure and disease progression.

Anteris Chief Medical Officer, Chris Meduri, M.D., commented: “The one-year data for DurAVR® THV continues to validate its groundbreaking hemodynamic performance, demonstrating sustained excellent effective orifice area (EOA) and low mean gradients. Most notably, this is the only transcatheter valve to show zero prosthesis-patient mismatch (PPM) in small annuli patients—an achievement that sets a new standard in TAVR. PPM is a well-established predictor of valve failure and disease progression, and eliminating it has profound implications for long-term patient outcomes. These results reinforce the transformative potential of DurAVR® as we move toward pivotal trials.”

Sixty-five (65) patients have completed the primary endpoint measure at 30 days (previously reported as rolling cohorts at multiple medical conferences through 2023-2024). The DurAVR® THV System continues to demonstrate a consistent safety and efficacy profile, with high implant success across the clinical program.

The one-year data builds on the existing body of clinical evidence and will be included in the planned Investigational Device Exemption (IDE) submission to the U.S. FDA to seek approval to conduct the DurAVR® THV randomized, global pivotal study.

\*Prosthesis-patient mismatch (PPM) happens when a prosthetic valve, after being implanted, doesn't have a large enough opening (EOA) to accommodate the patient's blood flow needs, based on their body size. The result is higher than expected gradients. PPM affects a significant proportion of transcatheter aortic valve (TAVR) patients, particularly patients with a small aortic annulus and has been associated with impaired long-term survival following surgical aortic valve replacement (SAVR)<sup>2</sup>.

<sup>1</sup> Herrmann HC, Mehran R, Blackman DJ, Bailey S, Möllmann H, Abdel-Wahab M, Ben Ali W, Mahoney PD, Ruge H, Wood DA, Bleiziffer S, Ramlawi B, Gada H, Petronio AS, Resor CD, Merhi W, Garcia Del Blanco B, Attizani GF, Batchelor WB, Gillam LD, Guerrero M, Rogers T, Rovin JD, Szerlip M, Whisenant B, Deeb GM, Grubb KJ, Padang R, Fan MT, Althouse AD, Tchétché D; SMART Trial Investigators. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med*. 2024 Jun 6;390(21):1959-1971. doi: 10.1056/NEJMoa2312573. Epub 2024 Apr 7. PMID: 38587261.

<sup>2</sup> Ferrara J, Theron A, Porto A, Morera P, Luporsi P, Jaussaud N, Gariboldi V, Collart F, Cuisset T, Deharo P. Prosthesis-Patient Mismatch in Small Aortic Annuli: Self-Expandable vs. Balloon-Expandable Transcatheter Aortic Valve Replacement. *J Clin Med*. 2022 Apr 1;11(7):1959. doi: 10.3390/jcm11071959. PMID: 35407567; PMCID: PMC8999619.

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## About Anteris

Anteris Technologies Global Corp. (NASDAQ: AVR, ASX: AVR) is a global structural heart company committed to designing, developing, and commercializing cutting-edge medical devices to restore healthy heart function. Founded in Australia, with a significant presence in Minneapolis, USA, Anteris is a science-driven company with an experienced team of multidisciplinary professionals delivering restorative solutions to structural heart disease patients.

Anteris' lead product, the DurAVR<sup>®</sup> Transcatheter Heart Valve (THV), was designed in partnership with the world's leading interventional cardiologists and cardiac surgeons to treat aortic stenosis – a potentially life-threatening condition resulting from the narrowing of the aortic valve. The balloon-expandable DurAVR<sup>®</sup> THV is the first biomimetic valve, which is shaped to mimic the performance of a healthy human aortic valve and aims to replicate normal aortic blood flow. DurAVR<sup>®</sup> THV is made using a single piece of molded ADAPT<sup>®</sup> tissue, Anteris' patented anti-calcification tissue technology. ADAPT<sup>®</sup> tissue, which is FDA-cleared, has been used clinically for over 10 years and distributed for use in over 55,000 patients worldwide. The DurAVR<sup>®</sup> THV System is comprised of the DurAVR<sup>®</sup> valve, the ADAPT<sup>®</sup> tissue, and the balloon-expandable ComASUR<sup>®</sup> Delivery System.

## Forward-Looking Statements

This announcement contains forward-looking statements, including the time for the presentation of the one-year data results and the inclusion of the one-year data in the IDE submission. Forward-looking statements include all statements that are not historical facts. Forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “budget,” “target,” “aim,” “strategy,” “plan,” “guidance,” “outlook,” “may,” “should,” “could,” “will,” “would,” “will be,” “will continue,” “will likely result” and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described under “Risk Factors” in Anteris' Annual Report on Form 10-K for the fiscal period ended December 31, 2024 that was filed with the SEC and ASX. Readers are cautioned not to put undue reliance on forward-looking statements, and except as required by law, neither ATL or Anteris assume any obligation to update any of these forward-looking statements to conform these statements to actual results or revised expectations.

## Authorisation and Additional information

This announcement was authorised for release on the ASX by the Board of Directors.

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