Anteris Announces Results for the First Quarter of 2025

MINNEAPOLIS, United States and **BRISBANE, Australia 14 May 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 reported financial results for the quarter ended March 31, 2025, and provided a corporate update.

First Quarter 2025 Highlights

- Investigational Device Exemption ("IDE") for the DurAVR® THV's global, pivotal clinical trial (the "PARADIGM Trial"), submitted to the FDA during the First Quarter
- Scale up for commencement of the PARADIGM Trial ongoing – including expanding the Clinical Specialist Team and contracting with planned centers in the U.S., Canada and Europe
- Clinical milestone of 100 patients successfully treated with the DurAVR® THV – comprised of de novo aortic stenosis cases including complex anatomies, and valve-in-valve patients
- Reported one-year clinical data for DurAVR® THV – demonstrating sustained, favourable hemodynamic outcomes, a consistent safety profile and high implant success
- Ongoing expansion of global manufacturing capacity to scale for the PARADIGM Trial and meet initial anticipated commercial demand
- Anteris included in the FTSE Russell 2000® Index
- Concluded the First Quarter with a cash position of $49.0m (A$78.0m)

"*Our focus this quarter has been on completing the substantial technical, clinical and regulatory work required to lodge our IDE application, which was successfully submitted during the period. We are also proud to have reached a major clinical milestone with over 100 patients treated with DurAVR®, the first new class of product in this space for many years – an incredible achievement which reflects the strength of our clinical program and growing physician confidence in our technology. Finally we continue to scale our field based Clinical Team, Manufacturing and Quality organizations to ensure we are able to meet the demands of the PARADIGM Trial"* said Wayne Paterson, Vice Chairman and Chief Executive Officer of Anteris.

Business & Operations

DurAVR® THV Commercialisation Update

Preparations for the PARADIGM Trial

The proposed DurAVR® THV global pivotal registration trial has been formally designated as the PARADIGM Trial, signifying the trial's central role in the DurAVR® THV Clinical Development Program.

***PARADIGM**: A **P**rospective r**A**ndomized t**R**ial **A**ssessing the safety and effectiveness of the **D**urAVR b**I**omimetic valve designed for physiolo**G**ic flow compared to Co**M**mercial TAVR devices*

An IDE application for the PARADIGM Trial was submitted to the U.S. Food and Drug Administration (FDA) during the First Quarter. An approved IDE allows the investigational device (the DurAVR® THV) to be used

in a clinical study to collect safety and effectiveness data. The PARADIGM Trial is designed to provide the robust clinical evidence required to support an application to the FDA for Premarket Approval ("PMA"*) in the United States, with CE Mark approval anticipated to progress in parallel to the PMA. The Company remains on track to commence the PARADIGM Trial in the third quarter of 2025, pending FDA approval of the IDE.

The naming of the PARADIGM Trial reflects both the paradigm-shifting hemodynamic performance observed to date in over 110 patients treated with the DurAVR® THV and the trial's head-to-head, comparative design. It is proposed that patients will be randomized 1:1 to either the DurAVR® treatment arm or to a commercially available device in the control arm (SAPIEN or Evolut series THV).

Patients with an existing failed surgical valve, needing valve-in-valve ("ViV") TAVR are proposed to be enrolled in a separate parallel registry. This is intended to support the Company's plans for the ViV market opportunity.

Scale up activities for the PARADIGM Trial

The Company continues to develop infrastructure to support the PARADIGM Trial including building out the global Clinical Specialist Team to provide on-site expert clinical support in addition to working with its Contract Research Organisation to engage with planned centers and investigators in the U.S., Canada and Europe. These teams will provide oversight and guidance to site based clinical staff to ensure appropriate use of the DurAVR® THV System, high-quality data collection and adherence to regulatory and protocol requirements throughout the PARADIGM Trial. These preparatory steps are intended to increase the speed of enrolment following IDE approval.

Clinical Milestone – 100 patients successfully treated with the DurAVR® THV

During the First Quarter, Anteris achieved a major clinical milestone when the 100th patient was successfully treated with the DurAVR® THV System. This marks a significant achievement for Anteris and its goal to restore heart valve patients to healthy function.

The patients included de novo (first time) aortic stenosis cases, some with complex anatomies such as bicuspid aortic valve patients. Additionally, a cohort of ViV patients were treated—these are patients who underwent a previous surgical or transcatheter aortic valve replacement procedure (SAVR or TAVR) and subsequently experienced failure of their bioprosthetic aortic valve.

At the end of the First Quarter, 65 of the 100 patients treated with the DurAVR® THV, had successfully completed the primary endpoint measures of safety and efficacy including hemodynamic benefit at 30-days post implant. These results are both clinically relevant and significantly differentiated to current therapies available to aortic stenosis patients.

Clinical Data – One-year patient outcomes for DurAVR® THV patients

Anteris released one-year clinical data for patients treated with the DurAVR® THV, as a late breaking clinical trial podium presentation by Rishi Puri, M.D. PhD, at the Sydney Valves structural heart conference in March 2025. The one-year data, which was included in the IDE submission to the FDA, demonstrated a consistent safety and efficacy profile, with high implant success across the clinical program. Highlights from the one-year data include:

- **Favorable hemodynamics sustained to one-year**: DurAVR® THV demonstrated an Effective Orifice Area (EOA) of 2.1 $\pm$ 0.2 cm^2, a Mean Pressure Gradient (MPG) of 8.6 $\pm$ 2.6 mmHg and Doppler Velocity Index (DVI) of 0.58.

- **Strong safety profile at one year**: No valve or cardiovascular related mortality. Importantly, there was no prosthesis-patient mismatch (PPM) reported in small annuli patients with aortic annulus area of 395.80 ± 37.26 mm^2, while current commercial devices have rates between 11.2% to 35.3% PPM[1], a predictor of valve failure and disease progression.

The clinical presentation is available on the Company's website.

Expansion of global manufacturing capacity

During the First Quarter, the Anteris team continued to expand global manufacturing capacity to scale for the PARADIGM Trial. All production (DurAVR® THV, ComASUR® Delivery System, crimper, E-sheath) are being scaled into new ISO Qualified Clean Room facilities, increasing manufacturing capacity to at least three times the 2024 capacity levels. The transition to the new facilities aims for a reliable and scaled inventory supply to support the anticipated commencement of the PARADIGM Trial. In addition, the gold-standard ADAPT® tissue for the DurAVR® THV will be sourced from both the U.S. and Australia moving forward to mitigate supply chain risks. This progress reflects the strategic deployment of capital into infrastructure that supports operational readiness and long-term growth capacity for clinical and commercial success.

First Quarter 2025 Financial Results

The financial results for Anteris for the quarter ended March 31, 2025 compared to March 31, 2024 are reviewed below. All amounts in $ refer to US dollars.

Net sales during the three months ended March 31, 2025 were $0.6 million, a decrease of $0.2 million (27%), compared to $0.8 million for the same period in the prior year, primarily due to lower demand for tissue products in 2025.

Loss after Income Tax was $21.9 million for the three months ended March 31, 2025, an increase of $5.8 million (36%) compared to $16.2 million for the same period in the prior year.

- R&D expenses during the three months ended March 31, 2025 were $16.5 million, an increase of $4.9 million (42%) compared to $11.6 million for the same period in the prior year. This is primarily due to $3.5 million relating to the upscaling of manufacturing capabilities including process design and validation activities and the expansion of headcount and $1.5 million relating to preparatory activities linked to the PARADIGM Trial, including clinical costs associated with the enrollment of additional patients;

- Selling, general and administrative expenses during the three months ended March 31, 2025 were $5.7 million, a decrease of $0.8 million (13%) compared to $6.5 million for the same period in the prior year, primarily due to a reduction of $1.2 million relating to costs incurred in the first quarter of 2024 associated with the plans to re-domicile, list on Nasdaq and conduct our initial public offering, partly offset by a $0.8 million increase in legal, tax and compliance costs linked to dual listing requirements and other operational matters. There was also a decline in share based payment expense of $0.5 million.

Anteris refers to the detailed Financial Information contained in its Form 10-Q filing, including the Management Discussion & Analysis and the risks described therein.

Corporate and Financing Activities

In January 2025, TD Cowen, Barclays and Cantor, the Underwriters to the December 2024 US IPO, partially exercised the green shoe option granted by Anteris. This green shoe option was in respect of 78,481 shares

of Common Stock at the purchase price of US$6.00 per share, less underwriting discounts and commissions, to raise a further $0.47 million.

During the First Quarter, Anteris was included as one of seven IPO additions to the FTSE Russell 2000® Index, effective as of March 24, 2025. The FTSE Russell 2000® Index measures the performance of the small-cap segment of the US equity market. The FTSE Russell® 2000 Index is a subset of the Russell 3000® Index which is designed to represent approximately 98% of the investable US equity market.

[1] 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, Attizzani 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.

*A Premarket Approval (PMA) application requires a high level of clinical evidence to demonstrate reasonable assurance of safety and effectiveness for the intended use. Randomized controlled trials are generally considered Level 1 evidence, the highest level for determining the effectiveness of interventions in evidence-based medicine given RCTs mimimize bias and allow a clear comparison between treatment groups.

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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® 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® 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® THV is made using a single piece of molded ADAPT® tissue, Anteris' patented anti-calcification tissue technology. ADAPT® 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® THV System is comprised of the DurAVR® valve, the ADAPT® tissue, and the balloon-expandable ComASUR® Delivery System.

Forward-Looking Statements

This announcement contains forward-looking statements. Forward-looking statements include all statements that are not historical facts, including the objectives of and plans for Anteris' studies and trials, the timing of the PARADIGM Trial, the goals of the expansion of the global manufacturing capacity and the sourcing of ADAPT® tissue for the DurAVR® THV in the future. 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 Securities and Exchange Commission and ASX. Readers are cautioned not

to put undue reliance on forward-looking statements, and except as required by law, Anteris does not 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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