

Anteris Technologies Announces First U.S. Patients Treated in Global Pivotal PARADIGM Trial

MINNEAPOLIS, United States and BRISBANE, Australia 6 May 2026 (AEST): 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 that the first patients in the United States have been enrolled and successfully treated in the DurAVR[®] Transcatheter Heart Valve (“THV”) global pivotal trial for patients with severe calcific aortic stenosis (the “PARADIGM Trial”). The procedures were performed by Azeem Latib, M.D. at Montefiore Medical Center, New York, United States.

“Performing the first U.S. cases in the global PARADIGM Trial is a significant achievement for trial investigators, and our early procedural experience with the DurAVR[®] THV System has been highly encouraging,” said Dr. Latib, Principal Investigator and Director of Interventional Cardiology and Director of Structural Heart Interventions at Montefiore. “PARADIGM is specifically designed to answer clinically meaningful questions and go beyond the usual safety metrics and hemodynamics by also looking at the impact of flow patterns on left ventricular recovery. Initiating enrollment represents a critical step toward generating the evidence needed to inform future patient care.”

“Following CMS approval, the Anteris team and our physician partners worked closely together to achieve first patient enrolments within the week. This marks a major milestone for the PARADIGM Trial as our US study sites come on line and expand recruitment capability,” said Wayne Paterson, Vice Chairman and Chief Executive Officer of Anteris.

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About the PARADIGM Trial

The PARADIGM Trial is a prospective randomized controlled trial which will evaluate the safety and effectiveness of the DurAVR[®] THV compared to commercially available transcatheter aortic valve replacements (TAVRs).

This head-to-head study will enrol approximately 1000 patients in the ‘All Comers Randomized Cohort’ with 1:1 randomization of patients who will receive either the DurAVR[®] THV or TAVR using commercially available and approved THVs. The PARADIGM Trial will assess non-inferiority on a primary composite endpoint of all-cause mortality, all stroke and cardiovascular hospitalization at one year post procedure.

For further information, please refer to [ClinicalTrials.gov NCT07194265](https://ClinicalTrials.gov/NCT07194265).



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, was designed in collaboration 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, including the quotes contained herein. 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, 2025 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 Chief Executive Officer.

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