FDA Approves Anteris' DurAVR® THV Global Pivotal Trial (the "PARADIGM Trial")

***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*

MINNEAPOLIS, United States and **BRISBANE, Australia 3 November 2025:** Anteris announced today it has received U.S. Food and Drug Administration (FDA) approval to initiate PARADIGM, its global Investigational Device Exemption (IDE) clinical trial which is designed to evaluate the DurAVR® Transcatheter Heart Valve (THV) in patients with severe calcific aortic stenosis and to support a future PMA* submission.

"We are extremely pleased to receive FDA approval for the PARADIGM Trial, which allows us to commence patient recruitment in the United States**. This milestone, together with the recent launch of the trial and first patients treated in Denmark, represents a significant achievement and a key step forward in advancing this life-saving technolgy worldwide for patients living with aortic stenosis, a debilitating and progressive condition," commented Vice Chairman and CEO, Wayne Paterson.

The PARADIGM Trial is co-chaired by Dr. Michael J. Reardon, Allison Family Distinguished Chair of Cardiovascular Research and Professor of Cardiothoracic Surgery at the Houston Methodist Hospital, Texas and Professor Stephan Windecker, Chairman of the Department of Cardiology at Bern University Hospital, Switzerland.

About the PARADIGM Trial

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

This head-to-head study will enroll approximately 1000 patients across the Unites States, Europe and Canada 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.

The PARADIGM Trial is designed to provide the robust clinical evidence required to support an application to the FDA for Premarket Approval in the United States, with CE Mark approval anticipated to progress in parallel to the PMA.

For further information, please refer to ClinicalTrials.gov (ClinicaTrials.gov ID NCT07194265).

*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.

**Subject to Institutional Review Board (IRB) approval

860 Blue Gentian Road,
Suite 340
Eagan, MN, 55121
United States
T: +1 651 493 0606
info.us@anteristech.com

Anteris Technologies Global Corp.
BRISBANE | MINNEAPOLIS | GENEVA | MALAGA
anteristech.com

Toowong Tower, Level 3, Suite 302
9 Sherwood Road, Toowong
QLD 4066, Australia
T: +61 1300 550 310
info.au@anteristech.com
ARBN: 677 960 235

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 including statements regarding the intent for the PARADIGM Trial. 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.

For more information:

Investor Relations
investor@anteristech.com
Debbie Ormsby
Anteris Technologies Global Corp.
+61 1300 550 310 | +61 7 3152 3200

Investor Relations (US)
mchatterjee@bplifescience.com
Malini Chatterjee, Ph.D.
Blueprint Life Science Group
+1 917 330 4269

Website	www.anteristech.com
X	@AnterisTech
LinkedIn	https://www.linkedin.com/company/anteristech