ASX ANNOUNCEMENT

25 October 2023

Anteris Reports Unprecedented Positive Hemodynamic Results from the Interim Analysis of its US-EFS Trial for DurAVR™ THV

Brisbane, Australia and Minneapolis, USA: Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) reports data from its US Early Feasibility Study (EFS) for DurAVR™ Transcatheter Heart Valve (THV), a new class of aortic valve replacement (AVR) and the world's only biomimetic, single-piece transcatheter aortic valve.

The primary and key secondary endpoints of the US-EFS include safety and efficacy assessments such as success of implantation at the anatomically accurate position, and hemodynamic performance assessments including effective orifice area (EOA), mean pressure gradient (MPG), paravalvular leak (PVL) and Doppler Velocity Index (DVI). Patient outcomes such as stroke, myocardial infarction, life-threatening bleeds, and all-cause mortality are to be reported at 30 days, and 1-year post implantation.

The discharge interim analysis results include:

No. of patients = 15

Average Age: 81

% Female: 64%

Area-derived mean annulus diameter (mm) = 22.2 +/- 0.78

- Mean Effective Orifice Area (EOA) at discharge = 2.36 cm^2
- Mean Pressure Gradient (MPG) at discharge post-implantation = 7.8 mmHg
- Doppler Velocity Index (DVI) at discharge post-implantation = 0.71 V
- No paravalvular leaks (PVL) were observed in 93% of subjects and 7% had mild PVL. No moderate or severe PVL was observed.
- The permanent pacemaker rate within discharge = 0%
- Stroke rate at discharge = 0%
- Myocardial infarctions at discharge = 0%
- Life threatening bleeds at discharge = 0%
- All-cause mortality at discharge = 0%

This US EFS Study (Clinicaltrials.gov ID: NCT05712161) was initiated in quarter 3 2023. The Study's Primary Investigators are Dr Azeem Latib, and Dr Gorav Ailawadi, Chairman and Helen F. and Marvin M. Kirsh Professor of Cardiac Surgery at the University of Michigan – Study National Principal Investigator (Cardiac Surgery). Dr Mike Reardon, Chair of Cardiovascular Research at the Houston Methodist De Bakey Heart and Vascular Centre, is its Study chair. The FDA has categorized DurAVR™ in this study as a CMS Category B device, which permits the device to be sold during the study.

Dr. Chris Meduri, Anteris' Chief Medical Officer, commented:

"While we still await 30-day hemodynamic and all-cause mortality results from this trial, the discharge timepoint is a key early indicator of how interventional cardiologists judge the success of a TAVR implantation. The unparalleled hemodynamic results (EOA, MPG, DVI) show that our single-piece, biomimetic product, DurAVR™, can restore healthy normal pre-disease blood flow in acutely symptomatic patients. This data surpasses what is seen with commercial bioprosthetic valves available to date, and makes me, a practicing interventional cardiologist, very excited to bring this product to my patients in due course.

Wayne Paterson, Anteris' Chief Executive Officer, commented:

The US-EFS study was a critically important milestone in our journey to bring a new class of TAVRs into the market. Our US-EFS results not only corroborate what we have seen in the First-in-Human trial (N=20) but surpass all expectations. We are extremely proud of these landmark results and grateful to the physicians and patients who participated in the study.

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About Anteris Technologies Ltd (ASX: AVR)

Anteris Technologies Ltd (ASX: AVR) is a structural heart company committed to designing, developing, and commercialising innovative medical devices. Founded in Australia, with a significant presence in Minneapolis, USA (a MedTech hub), Anteris is science-driven, with an experienced team of multidisciplinary professionals delivering transformative solutions to structural heart disease patients.

The Company's lead product, DurAVR™, is a transcatheter heart valve (THV) for treating aortic stenosis. DurAVR™ THV was designed in partnership with the world's leading interventional cardiologists and cardiac surgeons. It is the first transcatheter aortic valve replacement (TAVR) to use a single piece of bioengineered tissue. This biomimetic valve is uniquely shaped to mimic the performance of a healthy human aortic valve.

DurAVR™ THV is made using ADAPT® tissue, Anteris' patented anti-calcification tissue technology. ADAPT® tissue has been used clinically for over 10 years and distributed for use in over 50,000 patients worldwide.

The ComASUR™ Delivery System was designed to provide controlled deployment and accurate placement of the DurAVR™ THV with balloon-expandable delivery, allowing precise alignment with the heart's native commissures to achieve optimal valve positioning.

Anteris Technologies is set to revolutionise the structural heart market by delivering clinically superior solutions for significant unmet clinical needs.

Authorisation and Additional information

This announcement was authorised by the Board of Directors.

For more information:

Investor Relations (US)
Malini Chatterjee, Ph.D.
Managing Director
Blueprint Life Science Group
+1 917 330 4269

Investor Relations
investors@anteristech.com
Anteris Technologies Ltd
+61 1300 550 310 | +61 7 3152 3200

Website	www.anteristech.com
Twitter	@AnterisTech
Facebook	www.facebook.com/AnterisTech
LinkedIn	https://www.linkedin.com/company/anteristech