ASX ANNOUNCEMENT

9 August 2023

Montefiore Health System Enrolls Patients in the US Early Feasibility Study

Brisbane, Australia and Minneapolis, USA: Anteris Technologies Ltd, (Anteris or the Company) (ASX: AVR) reported today that DurAVR™ Transcatheter Heart Valve (THV), a new class of aortic valve replacement (AVR) and the world's only biomimetic, single-piece transcatheter aortic valve, was used to successfully treat patients as part of the DurAVR™ THV Early Feasibility Study (EFS or the Study) in the United States. The EFS is an essential step towards receiving FDA approval in the US and commercialisation of this innovative medical technology.

Dr Azeem Latib, Director of Interventional Cardiology, Director of Structural Heart Interventions at Montefiore Health System, New York, and Study National Principal Investigator (IC), performed the first group of US DurAVR™ THV procedures. This first group of severe aortic stenosis patients treated with DurAVR™ THV had intraoperatively, post-implant EOAs of 2.2cm^2, and average mean gradients of 4mmHg.

Dr Latib commented:
"Having previously travelled to Europe with Anteris to implant patients with DurAVR™ THV, I am delighted to note that the post-procedure patient outcomes seen in US patients at my centre corroborate with data reported from previous cohorts. The ability to use this device with such excellent hemodynamic results, as well as ease of use, is incredible progress in the treatment of patients with severe aortic stenosis. We look forward to many more cases in the near future".

The EFS Study is evaluating the safety and feasibility of DurAVR™ THV in the treatment of subjects with symptomatic severe native aortic stenosis (AS). Enrolling ≥15 subjects at 7 Heart Valve Centers of Excellence within the United States. Dr Mike Reardon, Chair of Cardiovascular Research at the Houston Methodist DeBakey Hospital, is the Study Chair. This is an FDA-designated category B study and approved by CMS for reimbursement.

The primary endpoint at 30 days post-implantation of this Study will assess safety and device feasibility. Further details of the Study can be found in the attached Appendix.

This US EFS Study data will pave the way for a pivotal registrational trial.

Wayne Paterson, CEO of Anteris Technologies, commented:
"The successful treatment of these patients in the United States is yet another important milestone on our path to commercialisation of the DurAVR™ TAVR system. The patients enrolled at Montefiore Hospital in New York this week add to our body of evidence that supports the use case of DurAVR™ THV and its clinical superiority and validates the reproducibility of our data and the stellar performance to date. Today's patients had excellent outcomes with intraoperative mean gradients of 4mmHg. This further supports the case that DurAVR™ is both clinically viable and will be an important product for the treatment of aortic stenosis in the future, giving patients and physicians alternatives to current therapies."

Dr Chris Meduri, CMO of Anteris Technologies, added:
"We are pleased with the excellent results achieved by Dr. Latib and the team at Montefiore. We look forward to sharing the results at TCT 2023."

ENDS

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 the treatment of aortic stenosis. DurAVR™ THV has been designed in partnership with the world's leading interventional cardiologists and cardiac surgeons and 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.

DurAVRTM 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 is 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 desired valve positioning.

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

Authorisation and Additional Information
This announcement was authorised by the Board of Directors.

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Appendix

FDA-approved EFS Protocol

Clinicaltrials.gov ID: NCT05712161
Title: Use of DurAVR™ THV System in Subjects With Severe Aortic Stenosis: Early Feasibility Study

Study Overview

Brief Summary:
To evaluate the safety and feasibility of DurAVR™ THV System in the treatment of subjects with symptomatic severe native aortic stenosis.

Detailed Description:
The primary objective is to assess the acute and long-term safety and feasibility of the DurAVR™ device in adult subjects with symptomatic, severe native aortic stenosis eligible for the transcatheter aortic valve replacement as assessed by the Heart Team at the enrolling institutions.

Design Details

Primary Purpose: Device Feasibility
Allocation: N/A
Interventional Model: Single Group Assignment
Interventional Model Description: A prospective, non-randomised, single arm, multi-centre study
Masking: None (Open Label)

Subjects will be consented to follow-up to 10 years.

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
All-cause mortality or disabling stroke	Mortality will be reported as rate of death/mortality at 30 days. Disabling stroke will be reported according to VARC-3 Guidelines	30 days
Technical success	Freedom from mortality, successful device implant, and freedom from surgery or intervention related to the device.	Immediate post procedure

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
All-cause mortality	Mortality would be reported as rate of death/mortality at 30 days.	30 days
Disabling stroke	Rate of disabling stroke according to VARC-3 guidelines	30 days
Major vascular, access-related, or cardiac structural complication	Complications according to VARC-3 guidelines	30 days
VARC-3 Type 2-4 bleeding	Rates of Type 2, 3, and 4 bleeding according to VARC-3 guidelines	30 days

Acute Kidney Injury stage 3 or 4	AKI stage 3-4 according to VARC-3 guidelines	30 days
Moderate or severe aortic regurgitation	Aortic regurgitation according to VARC-3 guidelines	30 days
New permanent pacemaker due to procedure-related conduction abnormalities	Rate of pacemaker interventions in subjects experiencing conduction abnormalities	30 days
Surgery or intervention related to the device, including aortic valve reintervention	Device related interventions	30 days

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Hospitalisation (or re-hospitalisation)	Hospitalisation (or re-hospitalisation). Any admission after the index hospitalisation or study enrolment to an inpatient unit or hospital ward for ≥24 h, including an emergency department stay. Hospitalisations planned for pre-existing conditions are excluded unless there is worsening of the baseline condition.	1 year
Leaflet thickening and reduced motion	Assessing causes of valve leaflet thickening and reduced leaflet motion, such as leaflet thrombosis, endocarditis, leaflet deterioration, and valve frame expansion issues.	1 year

The study will be conducted in the United States at the following locations:

- Abbott Northwestern Hospital, Minneapolis, Minnesota
- Montefiore Medical Centre, Bronx, New York
- Columbia University Medical Centre, New York, New York
- Cleveland Clinic Foundation, Cleveland, Ohio
- Tucson Medical Center, Tucson, Arizona
- University of Michigan, Ann Arbor, Michigan
- Houston Methodist DeBakey Hospital, Houston, Texas

The study chair is Michael Reardon, MD, Methodist DeBakey Hospital.
The study estimated primary completion date is Q3 2023 and the study completion (10-year follow-up) date is estimated to be December 2033.