

ASX ANNOUNCEMENT

17 October 2023

Anteris Completes DurAVR™ THV EFS enrolment

Brisbane, Australia and Minneapolis, USA: Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) reports completing enrolment in its FDA approved Early Feasibility Study (EFS or the Study) in the United States. DurAVR™ THV is a new class of biomimetic valve and the world's only balloon-expandable, single-piece transcatheter aortic valve. The EFS is an essential step towards receiving FDA clearance in the US for commercialization of this innovative medical technology.

The EFS is evaluating the safety and feasibility of DurAVR™ THV in the treatment of 15 patients with symptomatic, severe native aortic stenosis (AS). The Study's Primary Investigators are Dr Azeem Latib, *Director of Interventional Cardiology and Structural Heart Interventions at Montefiore Health System, New York* – Study National Principal Investigator (IC) 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 Study chair. Discharge data and 30-day data will be presented upon finalising collation and analysis.

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

“We are pleased with the excellent outcomes we have seen in the Study and we look forward to sharing the results. The data has the potential to change the treatment paradigm for Severe Aortic Stenosis Patients.”

Dr Azeem Latib, Director of Interventional Cardiology and Structural Heart Interventions (Montefiore Health System New York), commented:

“I am enthused to note the post-procedure patient outcomes seen in US patients not only corroborated with data reported from previous cohorts but exceeded them. The ability to use this device with such excellent haemodynamic results, as well as ease of use, is incredible progress in the treatment of patients with severe aortic stenosis.”

Wayne Paterson, Anteris CEO, commented:

“The completion of the 15 patient EFS enrolment marks another major milestone in the Company's progress towards commercial approval. With outstanding results attributable to DurAVR™'s unique first in class biomimetic design, the product has proven its clinical viability. The Company is extremely grateful to the physicians and patients who participated in this Study.”

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 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:

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