

ASX ANNOUNCEMENT

21 November 2023

Anteris Reports Outstanding 30-Day Haemodynamic Results from the DurAVR™ THV US EFS Trial

Brisbane, Australia and Minneapolis, USA: Anteris Technologies Ltd (**Anteris** or **the Company**) (ASX: AVR) reports 30-day data from the US Early Feasibility Study (EFS) for DurAVR™ Transcatheter Heart Valve (THV).

The preliminary results 30 days post-procedure included data from 12 out of the 15 enrolled patients (three patients awaiting scheduling), with a mean age of 81+/-7 years, 67% female, and mean annulus diameter of 22.2 +/- 0.8 mm. The following 30-day haemodynamic results are reported:

- Mean Effective Orifice Area (EOA) = 2.13 cm²
- Mean Pressure Gradient (MPG) = 7.9 mmHg
- Doppler Velocity Index (DVI) = 0.62

No paravalvular leaks (PVL) were observed at 30-day follow-up.

The 30-day haemodynamic results are consistent with those reported at patient discharge with no significant change in EOA or MPG values.

In addition to outstanding haemodynamic results, the trial has so far shown excellent safety data, with no incidence of stroke, myocardial infarction, life-threatening bleeds, or all-cause mortality. These patient outcomes will be reported again at 1-year post-implantation.

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

"These haemodynamics are unparalleled. There's other exciting things as well. This biomimetic valve not only allows us to have this acute improvement in flow from a classic haemodynamic performance, but also we've seen on cardiac MRI, normalization of laminar flow out of the aorta. It's also likely to have significant implications as we think about the long-term durability of the valve, stress on the leaflets, but also aortopathies, potentially inflammation, other things as well."

Dr Michael Reardon, Study Chair, commented:

"As a surgeon, we've known for decades that the bigger EOA you start with, the longer your valve is going to last, the better you're going to do both short-term and long-term. So not only will this be a great valve for older people, but for younger people who want to stay active, this is going to be a great valve."

Wayne Paterson Anteris CEO commented:

"This excellent trial data continues to show the benefits of the first in class biomimetic valve DurAVR™. Coupled with our premium anti-calcification treatment ADAPT® and our Balloon Expandable delivery system (ComASUR™) the Company has demonstrated real innovation in valve design leading to these results. We continue to build on our data which includes 39 TAVR patients and 50,000 ADAPT® patients across the world. 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, DurAVRTM, is a transcatheter heart valve (THV) for treating aortic stenosis. DurAVRTM 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.

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 ComASURTM Delivery System was designed to provide controlled deployment and accurate placement of the DurAVRTM 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.

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