

# ASX ANNOUNCEMENT

11 June 2024

## **Anteris Provides Data Update on First in Human Study of DurAVR™ THV Presented at New York Valves 2024**

Anteris Technologies Ltd (ASX: AVR), a structural heart company developing DurAVR™ THV, a new class of TAVI and the world's only balloon-expandable, single-piece biomimetic aortic replacement valve shaped to mimic the native human valve, today announced a summation of the Company's presentation at the New York Valves annual Conference held at the Jacob K. Javits Convention Center in New York City.

Dr João Cavalcante, Section Head, Cardiac Imaging, Allina Health Minneapolis Heart Institute and Scientific Director, Cardiovascular Imaging Core Lab and Research Center, presented new cardiac MRI data from the DurAVR™ THV First-in-Human (FIH) Study. The findings showed the restoration of normal flow and hemodynamics, leading to significant left ventricular mass regression in patients with symptomatic, severe aortic stenosis.

DurAVR™ THV demonstrated excellent post-procedure hemodynamic results in 41 patients, with large effective orifice areas (2.20 cm<sup>2</sup>), single-digit mean gradients (8.5 mmHg) and a Doppler Velocity Index (DVI) of 0.62. These hemodynamic results resemble those seen in healthy subjects. Dr Cavalcante commented that the current market-leading balloon-expandable valve would be unable to achieve these results in small annuli patients (mean annulus size: 22.57mm), before proceeding to explain the clinical relevance of healthy flow dynamics beyond traditional echo gradients.

Dr Cavalcante explained that aortic stenosis is not just a disease of the valve, it is also a disease of the arteries and the myocardium. In normal healthy aortic flow, the flow is laminar; there is little-to-no flow displacement (FD), the flow is non-eccentric and there is limited-to-no flow reversal (FRR) even in systole (when the ventricle contracts). Using cardiac MRI data courtesy of Dr Pankaj Garg, Dr Cavalcante explained the same phenomenon could be seen with DurAVR™ THV, which restored laminar flow with near equivalence to a normal healthy aortic valve. Studies performed on commercially available transcatheter valves, either balloon-expandable or self-expanding, do not appear to restore normal aortic flow.

- Normal Healthy Aortic Valve: FD = 10%, FRR = 1% (n=5)
- DurAVR™ THV: FD = 15%, FRR = 5% (n=11)
- Severe AS: FD = 46%, FRR = 23%
- Edwards Sapien 3: FD = 48%, FRR = 35%
- Medtronic Evolut R: FD = 25%, FRR = 4%
- CEP Magna Ease: FD = 27%, FRR = 30%

Dr Cavalcante commented "When we look at commercially available surgical or TAVR valves, we are still seeing abnormal flow patterns on cardiac MRI. The restoration of laminar flow, as we are seeing with this new DurAVR™ THV, is a byproduct of the intrinsic valve design and novel technology, which might have positive downstream implications to the arteries and consequently to ventricle, and ultimately to the patients".

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Dr Cavalcante also reported that in patients treated with DurAVR™ THV, cardiac MRI also detected a significant left ventricular mass index regression at 6 months post-TAVR. A recent meta-analysis<sup>1</sup> of other TAVR platforms demonstrated an average LV mass index regression of around 15 g/m<sup>2</sup>, in comparison to DurAVR™ THV, which demonstrated a difference of almost 20 g/m<sup>2</sup>.

The full downstream effect of restoring laminar flow will need to be further studied and validated in ongoing and future studies, including a larger pivotal imaging sub-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 55,000 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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<sup>1</sup> Mehdipoor, G., Chen, S., Chatterjee, S. *et al.* Cardiac structural changes after transcatheter aortic valve replacement: systematic review and meta-analysis of cardiovascular magnetic resonance studies. *J Cardiovasc Magn Reson* **22**, 41 (2020). <https://doi.org/10.1186/s12968-020-00629-9>

