

ASX ANNOUNCEMENT

20 June 2024

DurAVR™ THV First-in-Human Data Confirms Optimal Valve Positioning with the ComASUR™ Delivery System

Anteris Technologies Ltd (ASX: AVR) a structural heart company developing DurAVR™ THV, a new class of TAVR and the world’s only balloon-expandable, single-piece biomimetic aortic replacement valve shaped to mimic the native human valve, today announced new data from the DurAVR™ First-in-Human (FIH) Study. The latest cohort of 13 patients was undertaken to finalise and confirm the performance of the ComASUR™ Delivery System prior to commencement of the DurAVR™ THV pivotal, registration study (Phase 3).

The balloon expandable ComASUR™ Delivery System enabled controlled deployment and accurate placement of the DurAVR™ THV, facilitating precise alignment with the patients’ native aortic valve. 30-day data from this recent cohort demonstrated improved haemodynamic (blood flow) performance relative to earlier favourable clinical results reported in the DurAVR™ THV FIH Study (Cohorts 1-4) in addition to validating the predictability of the ComASUR™ Delivery System.

FIH 30-day Haemodynamic Data (Cohort 5): 13 Patients

Haemodynamic Parameters (blood flow measures)	Description	DurAVR™ THV	Market Leader Indicative Values*	Difference to Market Leader
Effective Orifice Area (EOA), cm ²	A higher EOA decreases the work the heart must do	2.25	1.58	42%
Mean Pressure Gradient (MPG), mmHg	A lower MPG decreases the work the heart must do	7.81	11.94	35%
Doppler Velocity Index	A higher DVI indicates improved blood flow	0.62	0.44	41%

*Hahn RT, Leipsic J, Douglas PS, Jaber WA, Weissman NJ, Pibarot P, Blanke P, Oh JK. Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. JACC Cardiovasc Imaging. 2019 Jan;12(1):25-34. Average annular area by CT for DurAVR™ patients: 396.23 +/- 34.86mm², average annular area for market leader patients: 385 to 439mm²

The DurAVR™ THV was successfully implanted in 100% of the 13 cases.

Wayne Paterson, Anteris Technologies Chief Executive Officer, commented “The DurAVR™ THV and the ComASUR™ Delivery System were designed in partnership with our Medical Advisory Board to deliver a highly differentiated, new class (biomimetic) of valve which can be easily deployed via a balloon expandable platform. This latest data confirms the DurAVR™ THV System (valve and delivery system) can deliver market leading haemodynamic performance in an intuitive, easy to use, balloon expandable platform’.

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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 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.

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