

ASX ANNOUNCEMENT

12 March 2024

Updated 30-day DurAVR™ THV Clinical Data First-In-Human (FIH) and Early Feasibility Study (EFS)

Brisbane, Australia and Minneapolis, USA

Anteris Technologies Ltd (ASX: AVR) (Anteris or the Company) today announced further data from the DurAVR™ First-In-Human Study and US Early Feasibility Study (EFS).

The data substantiates the paradigm shifting haemodynamic (blood flow) results reported to date with the DurAVR™ valve, a new class of biomimetic transcatheter heart valve (THV) designed to restore normal blood flow in aortic stenosis, a serious, life-threatening heart condition which occurs when there is a narrowing of the aortic valve.

The latest data includes 30-day results for all 28 patients treated in the First-In-Human Study (Cohorts 1-4) in addition to 30-day results for all 15 patients treated in the US Early Feasibility Study.

FIH 30-day Haemodynamic Data (Cohorts 1-4): 28 patients

Haemodynamic Parameters (blood flow measures)	DurAVR™ THV	
Effective Orifice Area (EOA), cm ² (↑)	2.13	A higher EOA decreases the work the heart must do
Mean Pressure Gradient (MPG), mmHg (↓)	7.9	A lower MPG decreases the work the heart must do
Doppler Velocity Index (DVI) (↑)	0.57	A higher DVI indicates improved blood flow

EFS 30-day Haemodynamic Data: 15 patients

Haemodynamic Parameters (blood flow measures)	DurAVR™ THV	Market Leader Indicative values*
Effective Orifice Area (EOA), cm ² (↑)	2.2	1.58
Mean Pressure Gradient (MPG), mmHg (↓)	7.5	11.94
Doppler Velocity Index (DVI) (↑)	0.64	0.44

*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: 389.3 ± 29.4mm², average annular area for market leader patients: 385 to 439mm²

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The data builds on the positive clinical results reported to date which demonstrate this new class of biomimetic valve outperforms the market leader, returning patients to a near normal haemodynamic (blood flow) state.

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.

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