

ASX ANNOUNCEMENT

13 June 2024

Anteris Provides Update on DurAVR™ THV Valve-in-Valve Experience Presented at New York Valves 2024

DurAVR™ ViV restores similar aortic valve gradients to initial post-surgical results

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 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 Anita Asgar, Institut de Cardiologie de Montreal, presented a series of cases from five high-risk patients who underwent valve-in-valve (ViV) procedures using DurAVR™ THV. The patients were treated under Health Canada's special access program (SAP) which allows health care professionals to access unlicensed medical devices, such as DurAVR™, for emergency use when conventional therapies have failed, are unavailable, or are unsuitable to treat a patient.

Unique Challenges of ViV Procedures

While TAVR procedures have revolutionized heart valve replacement, up to 30% of patients may eventually require a second valve due to deterioration of the first implant¹. Transcatheter ViV replacement is performed by implanting a transcatheter heart valve within a failing bioprosthetic aortic valve. The transcatheter ViV operation is a less invasive procedure compared with reoperative surgical aortic valve replacement however this repeat procedure presents unique challenges for both doctors and patients.

"Valve-in-valve procedures often force us to make difficult choices," explained Dr. Asgar. "Current TAVR devices may limit optimal valve function (hemodynamics) for these very sick patients, while others are operationally challenging to ensure access to coronary arteries."

Restoring Valve Hemodynamics with DurAVR™

ViV implantation with DurAVR™ THV successfully reduced aortic valve gradients to a level similar to the initial post-surgical valve gradient.

Average aortic valve gradients across the series of 5 cases:

- Post-surgical valve replacement gradient (8-13 years prior) = 13.82 mmHg
- Mean gradient prior to ViV = 58.60 mmHg
- 30 day core lab echo data post DurAVR™ ViV = 13.76 mmHg

No major complications were reported.

1. Giordana, F., Bruno, F., Controtto, F. *et al.* Incidence, predictors and outcomes of valve-in-valve TAVI: A systematic review and meta-analysis. *Int. J. Cardiol.* **316** (2020). <https://doi.org/10.1016/j.ijcard.2020.05.058>

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Dr Asgar commented “This data set of valve-in-valve patients highlights the impact of the DurAVR™ valve biomimetic design by restoring these patients’ hemodynamics to the performance of their initial surgical valve and is very encouraging for the wave of valve-in-valve patients that are coming in the future”.

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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