

ASX ANNOUNCEMENT

22 May 2023

First in Human Results Presented at EuroPCR with Simultaneous Publication in EuroIntervention

Key Highlights:

1. The DurAVR™ Transcatheter Heart Valve (THV) First-in-Human Study demonstrated promising haemodynamic performance sustained to 1 year and restoration of near-normal blood flow dynamics.
2. DurAVR™ THV demonstrated an outstanding safety profile: No mortality (all causes), no disabling stroke, no life-threatening bleeding, and no myocardial infarction were reported during any follow-up visits.
3. These encouraging preliminary First-in-Human study results will be further validated in an FDA-approved Early Feasibility Study (EFS) commencing soon.

BRISBANE, Australia and MINNEAPOLIS, USA, Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) is delighted to announce the publication of "Early safety and feasibility of a first-in-class biomimetic transcatheter aortic valve (DurAVR™)" in *EuroIntervention* <https://links.anteristech.com/3Os1pz7>. The publication reports interim results from the DurAVR™ First-in-Human (FIH) Study designed to evaluate the safety and efficacy of the DurAVR™ THV, a first-in-class biomimetic valve, in the treatment of patients with symptomatic severe aortic stenosis.

Interim Results:

- 13 patients were enrolled; the DurAVR™ THV was successfully implanted in 100% of cases with no device-related complications.
- One access site complication, one permanent pacemaker implantation, and one case of moderate aortic regurgitation occurred.
- No deaths, stroke, bleeding, reinterventions, or myocardial infarction were reported during follow-up visits.
- Favourable haemodynamic results inclusive of zero prosthesis-patient mismatch were observed at 6 months, and results were sustained at 1 year in patients who completed the 1-year follow-up at the time the paper was submitted.

In parallel to the publication, an expanded FIH data set incorporating post-procedural data for an additional seven recently enrolled patients was presented by Dr Susheel Kodali during a scientific session at EuroPCR 2023.

Post-procedure Haemodynamics (48hr TTE)

- Increased average Effective Orifice Area (EOA) by 307% from baseline – an indicator of increased long-term survival and exercise capacity.

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- Reduced mean pressure gradient (MPG) across the valve by 84% from baseline.

Susheel Kodali, MD, Columbia University Irving Medical Center, New York, USA, first author on the publication and an Investigator in the FIH study commented:

“In the short-term, the haemodynamics are amazing, and that’s one of the things I’m excited about...when you look at 3-D echo, the leaflets really open to the frame edge, and that’s different than what we see with other valves.”

Dr Chris Meduri, Anteris’ Chief Medical Officer, said:

“Preliminary results from the FIH study with DurAVR™ THV demonstrate a good safety profile with promising haemodynamic performance sustained at 1 year and restoration of near-normal flow dynamics. The results are encouraging, and we look forward to validating the data as we study more patients”.

ENDS

About Anteris Technologies Ltd (ASX: AVR)

Anteris Technologies Ltd is a structural heart company that delivers clinically superior and durable solutions through better science and better design.

Its focus is developing next-generation technologies that help healthcare professionals deliver consistent life-changing outcomes for patients.

Anteris’ DurAVR™ 3D single-piece aortic heart valve replacement addresses the needs of today’s younger and more active aortic stenosis patients by delivering superior performance and durability through innovations designed to last the remainder of a patient’s lifetime.

The proven benefits of its patented ADAPT® tissue technology, paired with the unique design of our DurAVR™ 3D single-piece aortic heart valve, have the potential to deliver a game-changing treatment to aortic stenosis patients worldwide and provide a much-needed solution to the challenges facing doctors today.

Authorisation and Additional information

This announcement was authorised by Mr Wayne Paterson, Chief Executive Officer.

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