

ASX ANNOUNCEMENT

16 January 2023

Update: 12 Month Results for Anteris DurAVR™ Transcatheter Heart Valve (THV) Aortic Stenosis First in Human Study

Key Highlights:

1. The DurAVR™ Transcatheter Heart Valve (THV) First-in-Human Study met all performance endpoints with remarkable hemodynamic function sustained to 12 months.
2. DurAVR™ THV demonstrated an outstanding safety profile. All safety endpoints were met: No mortality (all causes), no disabling stroke, no life-threatening bleeding, and no myocardial infarction at 12 months.
3. These encouraging preliminary First-in-Human study results will be further validated in an FDA-approved Early Feasibility Study (EFS) in early 2023.

BRISBANE, Australia and MINNEAPOLIS, USA, Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) is delighted to announce 12-month results from the DurAVR™ First-in-Human (FIH) Study designed to evaluate the safety and efficacy of the DurAVR™ THV in patients with symptomatic severe aortic stenosis.

DurAVR™ THV is a new class of aortic valve replacement device that utilises the patented ADAPT® anti-calcification process and innovative tissue-shaping technology in the world's first single-piece transcatheter heart valve.

DurAVR™ THV's unique, first-in-class biomimetic design replicates the normal blood flow of a healthy human aortic valve. This First-in-Human Study shows DurAVR™ THV restored normal, pre-disease blood flow, producing large effective orifice areas (EOA), enabling the valve to open widely with low mean pressure gradients (MPG). Fewer sutures preserve tissue integrity and reduce leaflet stresses with longer coaptation - all crucial precursors for valve durability, improved patient outcomes and survival.

The first five patients implanted with DurAVR™ THV continue to show stable, improved valve function with excellent safety at 12-month follow-up. Study results demonstrate:

1. Increased average Effective Orifice Area (EOA) by 294% from baseline, as observed at 30 days and 12 months – an indicator paramount for increased long-term survival and exercise capacity.
2. Reduced mean pressure gradient (MPG) across the valve by 85% from baseline, which remains consistent to 12 months.
3. Increased blood flow velocity through the valve with stable hemodynamics from baseline, as observed at 30 days and 12 months.
4. No mortality (all causes), disabling stroke, life-threatening bleeding or myocardial infarction was reported at 12 months.

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5. No device-related complications.
6. The 6-minute walk test distance (6MWT) measuring patient exercise capacity after aortic valve replacement improved by 32% from baseline, with a 17% improvement from the 30-day result at 12 months.

Mr Wayne Paterson, Anteris' Chief Executive Officer, said:

"This strong safety and hemodynamic data for DurAVR™ THV at 12 months reinforces the tireless work of the entire Anteris Team, presenting powerful, real-world evidence of the benefit Anteris technology delivers to aortic stenosis patients. DurAVR™ THV demonstrates its single-piece of shaped tissue and novel design result in biomimetic behaviours that mirror the function of a healthy human aortic valve. Furthermore, we see the restoration of severely stenotic aortic valves back to pre-disease states with normal function. This firmly establishes DurAVR™ THV in an entirely new class of replacement heart valves. These results represent a major clinical milestone and value catalyst in our journey to bring DurAVR™ THV to patients worldwide that need a better valve."

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

"The DurAVR™ THV demonstrates how meaningful and differentiated innovation translates into real clinical benefits for patients suffering from aortic stenosis. The preservation of the impressive hemodynamics and safety out to 12 months in this first-in-human study is very encouraging. We are excited to expand this study to the United States in the near future with recently FDA-approved early feasibility study (EFS)."

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 patient outcomes.

Anteris' DurAVR™ is a 3D-shaped, single-piece aortic heart valve replacement that 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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