

# ASX ANNOUNCEMENT

31 July 2023

## First Successful Implantation of DurAVR™ THV in a Valve-in-Valve Procedure

**Brisbane, Australia and Minneapolis, USA:** Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) reported today that for the first time, DurAVR™ THV, a new class of biomimetic valve and the world's only balloon-expandable, single-piece transcatheter aortic valve, was used in a valve-in-valve (ViV) procedure as part of Health Canada's **Special Access Program (SAP)**.

A ViV procedure is required for patients with a life-threatening situation wherein their current bioprosthetic aortic valve is failing due to calcification or structural deterioration, and a new heart valve must be implanted inside the failing valve. These patients are at high risk for another surgery and require a minimally invasive treatment option. Canada's SAP exists so that life-saving technology not currently available for commercial use in Canada can be provided when there are no other commercially available alternatives are suitable.

Dr. Anita Asgar, Co-Director of the Structural Heart Program at the Institut de Cardiologie de Montreal (Montreal, Canada), made the request to Health Canada to use the DurAVR™ THV in a patient with a failing valve that needed optimal hemodynamic results as well as a short frame height as there was very high risk of poor hemodynamic performance with a conventional ViV procedure. Dr. Asgar performed the procedure on an 84-year-old male and implanted a DurAVR™ THV inside the failed surgical aortic valve replacement (SAVR).

The procedure was successful. The hemodynamic performance of the valve was outstanding in such a complex patient. The patient had an 88% reduction in mean gradient which brought the patient back to a near-normal physiologic state with a final gradient of only 6mmHg after deploying the valve. These results mirror what DurAVR has seen in its extensive ViV bench-top studies.

### Dr. Asgar commented:

"The DurAVR™ THV provided a life-saving solution for a patient requiring a new valve to be implanted without compromising hemodynamic performance or future coronary access. These hemodynamic results are not seen with currently available products, which is important as there is a large need for a valve that can offer optimal hemodynamic performance in the valve-in-valve setting, particularly with a shorter frame height. Additionally, despite this being an incredibly complex case, using Anteris' ComASUR™ delivery system and deploying the valve was remarkably easy. The unique design of DurAVR™, including the low frame height and the single-piece design, makes the valve well-suited to address the needs of valve-in-valve patients".

### Chris Meduri, Anteris Technologies CMO, commented:

"This successful procedure further validates our extensive pre-clinical work in valve-in-valve as well as our extensive clinical experience in native aortic stenosis. This signals the viability of a purpose-built valve designed to achieve life-saving outcomes in a patient population currently treated with tradeoffs in mind. Eliminating that compromise would be widely beneficial to a rapidly growing population of patients whose current valve is failing."

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## About Anteris Technologies (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 the treatment of aortic stenosis. DurAVR™ THV has been designed in partnership with the world's leading interventional cardiologists and cardiac surgeons and 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™ 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 50,000 patients worldwide.

Controlled deployment and accurate placement of DurAVR™ THV is via Anteris' proprietary ComASUR™ Delivery System. This system allows precision 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 that meet significant unmet clinical needs.

## About Valve-in-Valve

ViV procedures represent an additional, rapidly growing patient population for the treatment of aortic stenosis. ViV procedures have increased more than 10 times from 2014 to 2019, representing about 6% of commercial transcatheter Aortic Valve Replacement cases in the U.S.<sup>1</sup> (Garcia, 2022).

1. Garcia, S. (2022, 9 18). *Fracturing Bioprosthetic THVs Shows Increased Mortality Risk, 'Modest' Hemodynamic Benefit, in ViV TAVR – Analysis*. Retrieved from CRTonline.org: <https://www.crtonline.org/news-detail/fracturing-bioprosthetic-thvs-shows-increased-mort>

## Authorisation and Additional information

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

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