ASX ANNOUNCEMENT

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ANTERIS REPORTS SUCCESSFUL INTERIM RESULTS FOR THE FIRST-IN-HUMAN TRIAL FOR DurAVR™

Brisbane, Australia and Minneapolis, USA, Anteris Technologies Ltd (ASX: AVR) reports the first-in-human DurAVR™ THV study met or exceeded its interim study objectives.

At the 30-day follow up point, the first five patients of the planned 10-patient study showed:

- All five subjects continued to do well with no reported adverse events (no death, stroke, myocardial infarction, reintervention).
- An average 86% improvement in mean gradient (standard measure of stenosis severity) from pre-treatment levels.
- Mean gradients were up to 50% lower than other TAVR devices when matched to annular size.[1] All patients are in the normal or near normal range when compared to the general population with normal valve function.
- Average Effective Orifice Area (EOA) was up to 45% larger than those reported with other TAVR devices in matched annular sizes.[2]
- No conduction (heart rhythm) disturbances due to the procedure.
- No clinically significant paravalvular regurgitation despite very complex and heavily calcified anatomy.
- Echocardiographic and CT analysis reported normal leaflet mobility, no leaflet calcification or thrombus generation.
- Echocardiographic and CT imaging data showed consistent laminar flow throughout the valve and long coaptation length in all five patients. Ostensibly, these features indicate lower leaflet strain leading to long term durability.
- The system also allowed for excellent commissural alignment; a significant patient benefit if future coronary intervention were required.
- A 20% increase from baseline in 6 min walk test (a measure of patient exercise tolerance). This is a 170% greater improvement than observed in studies of other TAVR valves.[3] This indicates a marked improvement in patients' functional status and exercise tolerance. The improvement in exercise capacity may be associated with the increased EOA (larger valve opening area due to its unique design) allowing optimal haemodynamics (blood flow) at rest and during exercise.[4] Exercise performance is a critical marker of cardiac health.

Dr. Paul Sorajja, an interventional cardiologist at Abbott Northwestern Hospital and one of the implanting physicians in this trial commented, "Due to its unique leaflet design, DurAVR™ continues to provide superior haemodynamics with a balloon expandable platform".

Dr. Vinnie Bapat, a cardiothoracic surgeon at the Minneapolis Heart Institute and another member of the team of implanting physicians in the trial stated, "DurAVR™ has been rationally engineered to provide ease of implantation of the valve for the doctor, immediate haemodynamic benefit for the patient post-implantation, and the potential to provide a long-term durable effect

which is of utmost importance when treating younger, low-risk patients. We are happy to see the patients on this trial doing so well with such impressive haemodynamic improvement, and are looking forward to enrolling the rest of the trial imminently".

"DurAVR™ continues to exceed very high expectations in a complex group of bicuspid and tricuspid patients. The haemodynamic performance as well as valve function is remarkable. Additionally, the lack of any conduction change (arrhythmia) across five patients is a testament to the engineering team's ingenuity and focus on improving all aspects of TAVR for patients. All signs continue to point to success in our mission of making available a TAVR that works better from the get-go and lasts longer," Anteris Chief Medical Officer, TAVR interventionalist Dr Chris Meduri (the study leader), commented.

"The excellent results observed so far are a function of the proprietary 3D single-piece leaflet design of DurAVR™ that mimics a native aortic valve. These numbers are even more remarkable considering this cohort had small annular anatomy. Furthermore, patients' functional status improved as did their exercise performance indicating early improvements in quality-of-life due to receiving DurAVR™. As the mean age of patients in this study is 73 this improvement in exercise performance is incredibly important and supports the use of DurAVR™ in this more active patient group who require a valve that lasts longer and works better than current solutions. The current data represents a small number of patients and should be viewed as such. However, we look forward to continuing the study with the next cohort as well as recruiting patients for our FDA IDE study and reporting more results during 2022," Anteris CEO Wayne Paterson said.

[1]Naidu et al. Measuring TAVR Prosthesis Gradient Immediately Post-Procedure May Underestimate its Significance. JACC CV Imag. 2021;15(1):120-121
[2]Hahn et al. Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. JACC CV Imag. 2019;12(1):25-34)
[3]Mack et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients/Supplementary Appendix N Engl J Med 2019; 380:1695-1705
[4]Gorlin et al. Dynamics of the circulation in aortic valvular disease., Am J Med. 1955 Jun;18(6):855-70

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 reproduce consistent life-changing outcomes for patients.

Anteris' DurAVR™ 3D single-piece aortic heart valve replacement addresses the needs of tomorrow'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 the Board of Directors.

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