ASX ANNOUNCEMENT

18 June 2024

Anteris Provides Update on Pivotal Trial Submission
US FDA has provided positive feedback on key elements of the study design

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 that following a pre-submission meeting with the US FDA, the agency has indicated support for key study design aspects.

Pre-Submissions are the most common type of the Q-Submission program; they permit companies to receive guidance from FDA review teams prior to a premarket submission (i.e. 510(k) or PMA[1]) or IDE[2].

Anteris has submitted a series of questions in accordance with the FDA guidelines which sought to confirm the main structure of the study; included in these are:

- *Structured as an International Study*; meaning sites outside of the US can participate in the study
- Randomization of DurAVR™ against commercially available TAVR
- Non-inferiority as primary study goal
- Primary composite endpoint of Death, Stroke, and Rehospitalization
- Inclusion of all patient risk stratifications (high, intermediate, low)

In addition to these points, the FDA has also indicated that a single-arm, valve-in-valve registry to run concurrently with the primary aortic stenosis arm is also acceptable.

This study will be the first randomized all risks head-to-head registration trial for TAVR, and as such is expected to generate interest from both the medical and regulatory communities.

Wayne Paterson commented "receiving this feedback from the FDA is an important milestone as we continue our progress toward study approval and completion. We are appreciative of the ongoing and close collaboration with the FDA as we now prepare the final stages of the submission process. This is the final study on the path to marketing approval for DurAVR™".

The company will submit its pivotal IDE including the proposed study design pending completion of the FDA required animal and bench tests which are currently ongoing.

1. A premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.
2. An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study.

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.

For more information:

Investor Relations
investors@anteristech.com
Anteris Technologies Ltd
+61 1300 550 310 | +61 7 3152 3200

Investor Relations (US)
Malini Chatterjee, Ph.D.
Managing Director
Blueprint Life Science Group
+1 917 330 4269

Website	www.anteristech.com
Twitter	@AnterisTech
Facebook	www.facebook.com/AnterisTechnologies
LinkedIn	https://www.linkedin.com/company/anteristech