

ASX ANNOUNCEMENT

5 October 2021

ANTERIS COMPLETES KEY ANIMAL STUDY FOR EFS SUBMISSION

Brisbane, Australia and Minneapolis, USA. Anteris Technologies Ltd (ASX: AVR) (Anteris or the Company) announces the successful completion of its final chronic animal study required for the FDA early feasibility study (EFS) submission on its proposed US TAVR clinical trial.

Formal histopathology results for the three-month study (in six sheep) will be available in approximately four weeks. Its key objectives were to assess (1) DurAVR[™] THV hemodynamic performance and (2) the *in vivo* response.

Preliminary findings showed:

- DurAVR[™] THV had fully functioning leaflets and haemodynamics resulting in zero mortalities within the study; and
- DurAVR[™] valve functioned well for the study's duration, including on the following criteria:
 - 1. Healing characteristics (e.g., pannus formation, tissue overgrowth);
 - 2. Effect of post implantation changes in shape and structural components (e.g., the presence of device angulation, bends, kinks) on haemodynamic performance;
 - 3. Haemolysis;
 - 4. Thrombus formation;
 - 5. Embolization of material from the implant site, delivery device or heart valve substitute, migration or embolization of the heart valve substitute;
 - 6. Biological response (e.g., inflammation, calcification, thrombosis, rejection, other unexpected interactions with tissues);
 - 7. Interaction with surrounding anatomical structures (e.g., leaflets, annulus, subvalvular apparatus); and
 - 8. Structural valve deterioration and/or non-structural valve dysfunction.

The early review of this data is consistent with observations from previous studies. Once the data is formally analysed it will be submitted to the FDA in the final dossier seeking approval to commence the first in human TAVR study.

ENDS

About Anteris Technologies Ltd (ASX: AVR)

Anteris Technologies Ltd is a structural heart company delivering clinically superior and durable solutions through better science and better design. Its focus is on developing next generation technologies that help healthcare professionals create life-changing outcomes for patients.

The Anteris DurAVR[™] aortic replacement valve addresses the acute need in terms of superior hemodynamic profile as well as chronic needs in its ability to sustain that profile longer over the lifetime of the patient.

Anteris Technologies Ltd Registered Office: Toowong Tower, Suite 302, Level 3, 9 Sherwood Rd, Toowong, Queensland, 4066 Customer Service

T +61 1300 550 310 | F +61 1300 972 437 | E info@anteristech.com | W anteristech.com

Brisbane • Minneapolis • Geneva • Malaga





The proven benefits of its ADAPT[®] tissue technology, paired with DurAVR[™]'s unique 3D singlepiece aortic valve design, has the potential to deliver a functional cure to aortic stenosis patients and provide a much-needed solution to the challenges facing heart surgeons today.

Authorisation and Additional information

This announcement was authorised by the Board of Directors.

For more information:

Hannah Howlett WE Communications E: <u>WE-AUAnterisTech@we-worldwide.com</u> P: +61 4 5064 8064 www.anteristech.com Twitter: @AnterisTech Facebook: www.facebook.com/AnterisTech

