ASX ANNOUNCEMENT

9 February 2023

FDA Grants Expanded Approval for the DurAVR™ Early Feasibility Study

BRISBANE, Australia and **MINNEAPOLIS, USA:** Anteris Technologies Ltd (**Anteris** or the **Company**) (ASX: AVR) is pleased to announce that the United States Food and Drug Administration (FDA) has granted expanded approval for the *DurAVR™ THV System in Subjects with Severe Aortic Stenosis: Early Feasibility Study (EFS).*

The expanded approval removes the previous conditions placed on the study and will allow Anteris to accelerate certain activities related to study execution. Specifically, approval by the Centers for Medicare & Medicaid Services will finalize the reimbursement level under the Category B designation previously granted by the FDA.

The DurAVR™ THV System is a new class of 'biomimetic' aortic heart valve replacement device and the world's first single-piece transcatheter heart valve, made with the company's patented ADAPT® anti-calcification process and innovative tissue-shaping technology. The EFS will evaluate the safety and feasibility of the DurAVR™ THV System in the treatment of subjects with symptomatic severe native aortic stenosis.

Mr. Wayne Paterson, Anteris' Chief Executive Officer, said:
"The DurAVR™ THV clinical program continues to gather significant momentum with the removal of conditions by the FDA further paving the way for our ground-breaking technology. We are excited to continue building our remarkable real-world evidence base amongst patients receiving DurAVR™ in the United States as we progress on our path to regulatory approval."

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 outcomes for patients.

Anteris' DurAVR™ 3D single-piece aortic heart valve replacement 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.

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.au@anteristech.com | **W** anteristech.com

Brisbane ▪ Minneapolis ▪ Geneva ▪ Malaga

Authorisation and Additional information

This announcement was authorised by the Board of Directors.

For more information:

Investor contact
Deanne Curry
GRACosway
E: investors@anteristech.com
M: +61 414 388 997

Media contact
Nick Howe
GRACosway
nhowe@gracosway.com.au
M: +61 407 183 221

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