ASX ANNOUNCEMENT

28 November 2022

FDA approves Early Feasibility Study for the DurAVR™ THV System

Brisbane, Australia and **Eagan, Minneapolis, USA:** Anteris Technologies Ltd (**Anteris** or the **Company**) (ASX: AVR) is pleased to announce the U.S. Food and Drug Administration (FDA) has conditionally approved the DurAVR™ Transcatheter Heart Valve (THV) System for investigational device exemption (IDE) application to commence an Early Feasibility Study (EFS).

The study will evaluate the safety and feasibility of the DurAVR™ THV System in the treatment of subjects with symptomatic severe native aortic stenosis. The FDA concluded the Company provided adequate data to support the initiation of a clinical study in the United States. The EFS will enroll 15 subjects at 7 Heart Valve Centers of Excellence within the United States. It is anticipated the study will commence in early 2023.

The FDA has categorized DurAVR™ in this study as a CMS Category B device, which permits the device to be sold during the study pending CMS approval.

“I am pleased and eager to begin the DurAVR™ THV EFS to further evaluate this promising novel technology. The single piece, native-shape valve design of the DurAVR™ THV represents an advancement to existing heart valve technologies. I am excited to see the potential of the DurAVR™ THV in treating patients suffering from severe aortic stenosis,” stated Dr Michael Reardon, Allison Family Distinguished Chair in Cardiovascular Research, Department of Cardiovascular Surgery, Professor of Cardiovascular Surgery, Houston Methodist Hospital, Houston, TX and Study Chair for the DurAVR™ THV Early Feasibility Study.

“The FDA approval to begin the DurAVR™ EFS is a critical milestone for Anteris achieving Pre-Market Approval in the United States. It is also another validation of the remarkable work done so far. This study will build upon clinical data from the DurAVR™ First-in- Human Study recently presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Boston USA and London Valves in London, England. I am extremely proud of the entire Anteris Team for achieving this pivotal milestone in the clinical development of the DurAVR™ THV System” said Dr. Chris Meduri , Chief Medical Officer Anteris Technologies.

“This study sets up 2023 to be a significant year of milestones and catalysts as we continue to build our remarkable base of evidence amongst patients who have had DurAVR™ implanted. In the next year, we will significantly expand the patient population implanted with DurAVR™, a new class of valve made with a first-in-class, single-piece, native-like valve design built upon our breakthrough ADAPT® tissue treatment that has years of real world experience ” said Wayne Paterson, Chief Executive Officer, Anteris Technologies.

DurAVR™ THV System is an investigational device, limited by federal law for investigational use only.

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.

Anteris is focused on 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 Anteris' 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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