

ASX ANNOUNCEMENT

27 March 2023

FDA Allows Manufacturing to Begin at Expanded Production Facility for DurAVR™ THV

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 determined Anteris has met the regulatory requirements for manufacturing DurAVR™ THV at the Company's newly expanded production facility in Maple Grove, Minnesota USA.

The FDA's determination will allow for expanded in-house production capabilities that will lead to significant cost savings for the Company, and increased production efficiency as we prepare to build DurAVR™ Transcatheter Heart Valves (THV) in anticipation of upcoming clinical studies.

DurAVR™ THV's produced at the Maple Grove facility will be made available to leading interventional cardiologists treating patients with severe aortic stenosis as part of the DurAVR™ THV Early Feasibility Study (EFS) and Global Pivotal Studies.

The expanded Maple Grove facility complements existing tissue engineering capabilities in Malaga, Perth, where the company's patented ADAPT® anti-calcification technology is manufactured, whilst expanding overall production capacity.

Mr. Wayne Paterson, Anteris' Chief Executive Officer, said: "The commencement of valve production for clinical use at our US Maple Grove facility introduces great efficiencies and reduces manufacturing costs and is within easy reach of the world's largest TAVR centres and cardiovascular market".

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.

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Authorisation and Additional information

This announcement was authorised by the Board of Directors.

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