

19 February 2019

## ASX ANNOUNCEMENT

### PROMISING INTERIM RESULTS FROM TAVR ANIMAL STUDY

Medical technology company Admedus Ltd (ASX: AHZ) is pleased to advise that interim data from the animal study of its single-piece 3D aortic valve suggest that the device can be implanted safely and has the potential to deliver meaningful clinical benefits.

Following the positive findings in this feasibility study, Admedus now confirms it could initiate a first-in-human clinical trial earlier than expected.

To date, five sheep have been implanted and will be monitored for five months. Echocardiographic data from the first four animals, at approximately four weeks after implantation, showed Effective Orifice Areas (EOA) with a range of 2- 2.5cm<sup>2</sup>. No regurgitation was observed, and there was a low-pressure gradient across the valves (4-6 mmHg).

“This study has demonstrated that these stentless valves can be implanted with reasonable ease, without any major adverse event,” said Prof Bart Meuris, Cardiac Surgeon at KU Leuven, where the study is being conducted.

“The echocardiograms revealed superior functional valves with optimal hemodynamic profiles. We support the progression to a first-in-human clinical trial, and believe clinical implantation of this device is certainly possible in the short term and can be beneficial to many patients.”

“The purpose of this feasibility study is to assess whether there is merit to progress to a larger animal study, and human clinical trials – and the results we have so far strongly support this,” said Dr Kiran Bhirangi, Admedus’ Chief Medical Officer.

“The findings are very encouraging for several reasons. The sheep model is well accepted and a good predictor of the effectiveness of the technology. The EOA, which is an important factor in enabling the flow of fluid, or blood, is significant, given that valves in the market today have an EOA of 1.6 to 2. While the Admedus single-piece valve has demonstrated an EOA up to 2.5, the researchers will continue to monitor, and report on the five-month explant

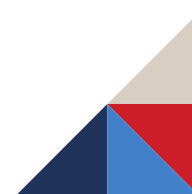
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data, but based on the current findings we are confident to take next steps towards human clinical trials.”

In laboratory tests, the Admedus TAVR valves were functional after 400 million cycles, which is equivalent to approximately ten years of human use. This is important because it demonstrates the durability of the valve over extended periods. The TAVR device utilises the Company’s ADAPT® technology, which has proven resistance to calcification and superior biomechanical properties. It is the first and only known single-piece 3D aortic valve in development.

“Calcification is a major issue for surgeons and patients today when treating valvular disease. Our ADAPT® tissue is the only product of its kind that has data demonstrating ten years without calcification or degradation. Combining this unique benefit with the first and only single piece 3D valve could be a major disruption in the treatment strategies for patients in the future,” said Wayne Paterson, Admedus CEO.

“ADAPT® TAVR would be a breakthrough for patients needing valve replacement. The TAVR market is expected to be \$US12 billion by 2025. If the earlier results translate to true clinical superiority, ADAPT® TAVR could be well placed to be the market leader.

“It’s important to acknowledge the preliminary nature of this data. However the combination of a novel single-piece 3D aortic valve and the ADAPT® technology which has been studied for ten years and is already used in over 16,000 patients is showing demonstrable clinical benefits,” Mr Paterson said.

“We see the development of our 3D portfolio, and the TAVR valve, as an integral part of Admedus’ global growth strategy. As we expand our portfolio from the paediatric space into the higher volume adult space serving many more patients across the spectrum.”

**ENDS**

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#### **About Admedus Limited**

Admedus (ASX: AHZ) is a medical technologies company delivering clinically superior solutions that help healthcare professionals create life-changing outcomes for patients. Our focus is on investing in and developing next-generation technologies with world-class partners, acquiring strategic assets to grow product and service offerings, and expanding revenues from our existing medical sales and distribution business. The Company has assets from research & development through clinical development and sales, marketing and distribution.

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