22 January 2020

ASX ANNOUNCEMENT

FIRST-IN-HUMAN SAVR TRIAL BEGINS Q1 2020

Admedus Limited (AHZ or the Company) announces approval for first-in-human surgical aortic valve replacement (SAVR) trial of its proprietary ADAPT® single-piece 3D aortic valve at the Leuven University Hospitals. The UZ Leuven Medical Ethics Committee approved the clinical trial protocol.

The SAVR market is estimated at $US3 billion by 2023 with more than 250,000 procedures performed in Europe and North America in 2018.

Professor Bart Meuris MD, PhD, a renowned Cardiac Surgeon at the University Hospitals, Leuven, Belgium, is conducting the clinical trial sponsored by Admedus Regen Pty Ltd, AHZ's wholly owned subsidiary. Fifteen patients will be enrolled in the study and will be followed up for 6 months after receiving implantation of the ADAPT® single-piece 3D aortic valve. The results from the study are expected to be available between Q1, 2021 and Q3, 2021.

[Clinical trial protocol link is

https://clinicaltrials.gov/ct2/show/NCT04178213]

The proposal follows Professor Meuris' confidence in the Company's prototype aortic valve after his recent investigation of the ADAPT® single-piece 3D aortic valve replacement in an ovine model (sheep). Encouraged by the results, Professor Meuris expects that the ADAPT® single-piece 3D aortic valve will produce similar positive results in human.

The Company's proprietary ADAPT® bio-scaffold material is notable for its durability and zero calcification virtues evidenced by ten years of published and peer reviewed data.

The ovine study was performed on six juvenile sheep. Juvenile sheep are a preferred model for bioprosthetic valve implantation.

Key results from the ovine study are as follows:

- Normal valve function postoperatively after aortic valve replacement with the ADAPT® single-piece 3D aortic valve.
- Follow-up up to 6 months revealed good and stable valve function.
- The valve tissue was easy to handle during surgical implantation, and thus might translate into clinical setting.

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- No material failure or fatigue of the valve material was observed.
- Echocardiography showed low gradients and no significant regurgitation across implanted valves.
- No contra-indication for a continuation towards a first-in-human trial with this prothesis.

Admedus Chief Executive Officer, Wayne Paterson commented, “This endorsement of our ADAPT® single-piece 3D aortic valve technology is an important next step to our development pathway. The ADAPT® single-piece 3D aortic valve has demonstrated excellent haemodynamics, both on the bench and in animal testing, and we expect to see that replicated in humans. The ADAPT® single-piece 3D aortic valve is uniquely designed as it is essentially the same valve whether it is placed surgically or by TAVR and will thus provide valuable information for the Admedus TAVR program as we move forward. Ultimately, we expect to see better outcomes for patients over the course of this study.”

ENDS

About Admedus Limited (ASX: AHZ)

Admedus Ltd is a structural heart company delivering clinically superior solutions that help healthcare professionals create life-changing outcomes for patients. Its focus is on developing next generation technologies with world class partners.

Authorisation and Additional information

This announcement was authorised by Mr Wayne Paterson, Chief Executive Officer.

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