

Anteris Technologies Ltd

15:50 22 Jan 2020

Admedus to begin first-in-human SAVR trial of single-piece 3D aortic valve this quarter

Admedus Ltd (ASX:AHZ) will begin the first-in-human surgical aortic valve replacement (SAVR) trial later this quarter of its proprietary ADAPT® single-piece 3D aortic valve.

This trial will take place at the Leuven University Hospitals and follows the UZ Leuven Medical Ethics Committee approving the clinical trial protocol.

The SAVR market is estimated at US\$3 billion by 2023 with more than 250,000 procedures performed in Europe and North America in 2018.

Renowned surgeon for trial

Professor Bar Meuris, a renowned surgeon at the University Hospitals in Leuven, Belgium, is conducting the clinical trial sponsored by Admedus Regen Pty Ltd, a wholly-owned subsidiary of Admedus.

Fifteen patients will be enrolled in the study and will be followed up for six 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.

"Important next step"

Chief executive officer Wayne Paterson said: "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."

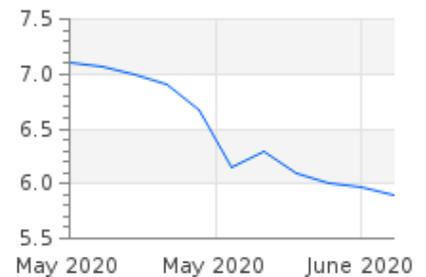
Notable for durability

Following Professor Meuris' recent investigation of the ADAPT® aortic valve replacement in an ovine model (sheep), he expects that the product will produce similar positive results in humans.

Price: 5.9

Market Cap: \$34.87 m

1 Year Share Price Graph



Share Information

Code: AVR

Listing: ASX

52 week High Low
7.5 5.65

Sector: Pharma & Biotech

Website: anteristech.com

Company Synopsis:

Anteris Technologies Ltd (ASX:AVR) is a structural heart company delivering clinically superior solutions that help healthcare professionals create life-changing outcomes for patients.

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The company's proprietary ADAPT® bio-scaffold material is notable for its durability and zero calcification virtues evidenced by 10 years of published and peer-reviewed data.

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

Key results from the study:

- Normal valve function postoperatively after aortic valve replacement with the ADAPT® single-piece 3D aortic valve;
- Follow-up up to six months revealed good and stable valve function;
- The valve tissue was easy to handle during surgical implantation and might translate into the clinical setting;
- No material failure or fatigue of the valve material was observed;
- Echocardiography showed low gradients and no significant regurgitation across implanted valves; and
- No contra-indication for a continuation towards a first-in-human trial with this prosthesis.

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