

## **ASX RELEASE**

### **Admedus initiates clinical study in reconstructing heart valves using CardioCel®**

- Admedus initiates clinical study in aortic tri-leaflet reconstruction using CardioCel - a key milestone for the Company
- Study undertaken in four leading heart centres in Europe and the US
- Total of 80 adult patients to be recruited with initial cases already enrolled
- Study to illustrate the utility and benefits of CardioCel in aortic valve reconstruction over valve replacements

#### **Brisbane, Australia 23rd September 2015**

Admedus Limited (ASX: AHZ) has today announced the initiation of a clinical study in aortic tri-leaflet heart valve reconstructions to repair aortic valvular disease such as aortic stenosis, using its cardiovascular bio-scaffold CardioCel.

CardioCel is on the market in North America, Europe and Asia and this study will aim to further support its use in heart valve repair and reconstructions. The study follows the positive completion of a world first pre-clinical study using CardioCel, undertaken in conjunction with KU Leuven University and announced on 10 September 2015.

"Off the back of a very successful pre-clinical study, we have now commenced a clinical study to provide further data to use CardioCel for complete aortic valve reconstructions," said Admedus CEO, Lee Rodne.

"This is an important study in aortic valve reconstruction, which has never been done before with a bio-prosthetic tissue like CardioCel. We believe the results will highlight the patient benefits of completely reconstructing the aortic valve with CardioCel compared to the current industry need of replacing it multiple times throughout a patient's life."

The study involves surgeons using CardioCel to reconstruct the three leaflets of the aortic valve as an alternative to replacing it with a bio-prosthetic valve. This provides an opportunity for autologous repair and the potential for patients to have a 'native' valve with better haemodynamic outcomes and overall improved health benefits compared to a replacement valve.

Aortic stenosis is the most common valvular heart disease in developed countries, with the incidence rate of around 25% in people over the age of 65 and prevalence increasing with age.<sup>1</sup> Last year, there were a 165,000 aortic valve replacement surgeries undertaken in the US alone.<sup>2</sup> While these were symptomatic patients, Admedus expects the market size for valve reconstruction will be larger once the benefits of treating patients earlier and more effectively is recognised.

The primary safety endpoint for the clinical study is to ensure same rates of in-hospital survival, while also looking for superior long-term benefits for patients, better haemodynamic outcomes, cell infiltration, regrowth of native tissue and long-term durability without calcification.

“As a surgeon, you often ask yourself are we really repairing the valve or are we just delaying the next heart valve operation or replacement. Where most patients with symptomatic aortic valve disease will be delayed to surgery, this study could prove that CardioCel could offer earlier intervention, with possible life-long benefits,” said Domenico Mazzitelli, cardiac surgeon and clinical study lead at the German Heart Centre Munich.

The study will enrol 80 adult patients at two European and two US sites, with initial cases already enrolled in the first week post ethics approval. Ethics approval has been received for the two European centres, KU Leuven University in Belgium and the German Heart Centre Munich, with US ethics approval expected in the coming months.

“While a majority of current aortic valve procedures follow the replacement strategy, we hope to show that reconstructing the valve with CardioCel is superior to replacing the valve and provides patients with long-term health benefits,” said Mr Rodne.

Patients in the clinical study will be reviewed 6, 12 and 24 months post-surgery to evaluate safety data and primary and secondary endpoints.

1. Cleveland Clinic, Aortic Valve Disease, 2014  
<http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/aortic-valve-disease/Default.htm>
2. Life Science Intelligence, Cardiothoracic & Inter. Cardio, LSI-PV-US118SU: U.S. Surgical Procedure Volumes from 2007-2014

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## **About Admedus Limited**

Admedus (ASX: AHZ) is a specialist healthcare company. 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, profitable medical sales and distribution business. The company has assets from research & development through clinical development as well as sales, marketing and distribution.

Admedus has commercialised its innovative tissue engineering technology for regenerative medicine in four continents. We also have a major interest in developing the next generation of vaccines with a Brisbane-based research group led by Professor Ian Frazer. The vaccine programmes target disease with significant global potential, such as Herpes and Human Papillomavirus.

Further information on the company can be found on [www.admedus.com](http://www.admedus.com)

## **About CardioCel®**

CardioCel is a type of cardiovascular bio-scaffold that can be used to repair congenital heart deformities and more complex heart defects. It is used to repair diseased paediatric and adult hearts. These repairs range from routine hole-in-the-heart operations to major vessel outflow tract repairs. The CardioCel scaffold may also be used to repair heart valves. CardioCel has been shown to allow tissue regeneration once implanted. Some researchers postulate that stem cells play an active role in tissue regeneration, suggesting that the product facilitates endogenous stem cells and other cells to regenerate and repair damaged tissue. CardioCel is the Admedus Group's lead regenerative tissue bio-implant used in repairing heart defects, including the repair of heart valves. It is engineered via the Admedus Group's proprietary ADAPT® tissue engineering process to produce a durable, collagen scaffold with handling properties preferred by surgeons that avoids calcification, while supporting native cell infiltration, growth and differentiation. CardioCel® is a registered trademark.