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Positive CardioCel® valve reconstruction data released at EACTS

- Clear advantages in successful aortic valve reconstruction with CardioCel® compared to replacement with a bio-prosthetic valve
- Study shows remodelling around CardioCel post-surgery
- Data released at European Association for Cardiothoracic Surgery (EACTS) meeting in Amsterdam on the 5th of October
- CardioCel now in 110 centres globally

Brisbane, Australia 6th of October, 2015

Admedus Limited (ASX: AHZ) has today announced positive data from its pre-clinical aortic tri-leaflet reconstruction study using CardioCel®. The study data was presented on the 5th of October by Professor Bart Meuris at the European Association for Cardiothoracic Surgery (EACTS) meeting in Amsterdam.

The results from the study show successful valve reconstructions and support the use of CardioCel in the complete reconstruction of aortic heart valves and aims to address the disadvantages found with existing bio-prosthetic valves.

"This study and data are extremely important as they clearly show the benefits of reconstructing heart valves with CardioCel compared to using a bio-prosthetic valve. It further illustrates the benefits of the ADAPT tissue engineering process and its ability to produce superior regenerative tissue products," said Admedus CEO Mr Lee Rodne

The study undertaken at KU Leuven University in Belgium examined nine leaflets replaced in three sheep. Results showed no or minimal calcification detected, with only minimal calcification seen around the sutures and a commissure. In addition, the valves were competent, demonstrating positive haemodynamics, with no leakage and excellent coaptation of the leaflets post reconstruction.

"The results from the study are very positive and some of the best results we have seen in this model," said Professor Bart Meuris, lead researcher at KU Leuven University.

After six months, new collagen had formed on both sides of the leaflet as a clear sign of post-surgery remodelling around CardioCel, with host fibroblasts detected within the CardioCel bio-scaffold. The six month time-frame in sheep is representative of over 10 years of data in adult patients.

The study results demonstrate that CardioCel, which is now used in 110 heart centres, shows clear advantages over replacement of the aortic valve or reconstruction with other tissues.

Admedus recently announced a follow on aortic tri-leaflet heart valve reconstruction clinical study using CardioCel to repair aortic valvular disease in patients. The clinical study will take place in Europe and the US to further support the use of CardioCel in heart valve repairs and reconstructions. KU Leuven Hospital has already received ethics approval to participate in the clinical trial.

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Additional study information

The purpose of the study was to examine the use of CardioCel in the reconstruction of aortic heart valves as an alternative to replacing them with a bio-prosthetic valve.

Prosthetic valves have been developed using xenograft tissues as leaflets and are surgically implantable, as well as deliverable by catheter. Whilst these technologies have improved on earlier technologies, prosthetic valves still do not enable full motion of the aortic valve and root and therefore result in suboptimal haemodynamics and can require multiple replacements throughout a patient's life.

In contrast, reconstructing the heart valve with CardioCel has the potential to be a life-long solution and patients can be treated by earlier intervention before requiring a replacement bio-prosthetic or mechanical valve.

In addition, a combination of improved haemodynamics, lack of calcification and post-implant remodelling as also seen with reconstructing the valves with CardioCel in previous studies, has the potential to address all of the disadvantages of existing bio-prosthetic valves and reconstruction techniques that utilise other tissues including autologous tissue.

The established sheep valve surgical model had an initial six animals implanted. Unrelated to the CardioCel tissue or valve function, three animals did not survive the post-surgery recovery period despite having fully reconstructed, functioning aortic heart valves. The three surviving animals had nine fully functional leaflets and valves, which remained in place until being explanted after six months post-surgery.

Echocardiography conducted during the study showed full valve function at one week, three months and six months post-surgery with no significant leakage. Macroscopic evaluation at termination confirmed complete coaptation of the intact, soft and pliable leaflets.

Histological evaluation showed remodelling of the leaflet with fibroblast infiltration and recellularisation and collagen deposition on the leaflets.

The results from the study indicate that reconstructing the aortic valve with CardioCel provides clear advantages over replacement of the aortic valve or reconstructing it with other tissues, which could be particularly important in both paediatric and adult patients.

The full data from this study will be published in the near future.

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

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.