

ASX ANNOUNCEMENT

Evidence of new tissue regeneration for CardioCel® in heart valve reconstruction study

- Allied's CardioCel® patch shows new tissue regeneration in heart valve reconstruction study
- No macroscopic calcification for Allied's CardioCel® treatment arm
- Data independently validated in the US and Australia

Brisbane, Australia, 28 November 2012

Allied Healthcare Group (ASX: AHZ) today announced the successful results of a pre-clinical study which used CardioCel® to reconstruct heart valves, and which showed its cardiovascular patches promote healing at the site of repair and other benefits.

The study demonstrated the outstanding performance of CardioCel® in the reconstruction of heart valves compared to the control, and notably that valves in the CardioCel® repaired group demonstrated significantly reduced calcification versus the control as well as minimal thickening of the tissue.

The histology data showed that after eight months there had been significant new tissue growth on both sides of the implanted CardioCel® patch, consisting of collagen and several different cell types, which are typically found in a healthy cardiovascular healing process as well as in heart valves.

In the study there was no evidence of macroscopic calcification of the CardioCel® implant on echocardiography (heart ultrasound) and in molecular measurement of extractable calcium, the active CardioCel® tissue had 40% less calcium than the control native autologous tissue.

"These results are remarkable, particularly regarding evidence that the CardioCel® patch material appears to enable tissue regeneration, opening up the possibility for CardioCel® treated valves to regenerate without additional intervention or assistance," said Lee Rodne, Allied Healthcare Group Managing Director.

"The demonstration of effective tissue regeneration without adding external stimulation like stem cells or growth factors is a major new finding from this study."

The histology results were independently assessed by Prof. Frederick J. Schoen, M.D., Ph.D, Executive Vice-Chairman, Department of Pathology, Brigham and Women's Hospital and Professor of Pathology and Health Sciences and Technology (HST), Harvard Medical School. Calcification levels were independently quantified by the Murdoch University research group.

In his conclusion, Prof Frederick J. Schoen said, "No apparent significant adverse effects were present. Based on the experience in the present study, CardioCel® pericardium appears to be a suitable bioprosthetic substitute for valve reconstruction procedures and consideration as an alternative to autologous pericardium."



"As well as tissue regeneration, further evidence of the lack of calcification in the CardioCel[®] tissue is very encouraging. Reduced calcification should result in the reduction of repeat surgeries, and therefore the reduction in unnecessary patient risk, stress and cost, promoting a lifelong solution for patients. These results provide further support to the importance and benefits of CardioCel[®] in the area of tissue repair, reconstruction and regeneration," said Bob Atwill, Allied Executive and CEO of the Regenerative Medicine Franchise.

The study was undertaken in collaboration with paediatric cardiac surgeon Professor Christian Brizard, from The University of Melbourne.

The CardioCel[®] scaffold appears to attract endogenous stem cells which allow "normal" cell growth, proliferation and differentiation into fully functional valve tissue. Current research indicates that a tissue matrix becomes incorporated into native tissue over time. These study results show that CardioCel[®] becomes enveloped with endothelial cells via normal cell growth, suggesting it is 'invisible' to the recipient immune system and becomes native tissue over time.

These results expand the potential for CardioCel[®] and open up opportunities to develop additional ADAPT[®] engineered tissue products. The independent validation of these latest results confirms the regenerative performance of the ADAPT[®] treated tissue and provides an opportunity to transform valve reconstructive surgery, along with expanding opportunities in congenital heart disease repair surgery.

"These regenerative results, in one of the most challenging models, are significant as native tissue has regenerated after 8 months. From a commercial perspective, as CardioCel[®] is a Class III medical device, it has a much more straightforward and cost effective route to market compared to biologic agents and stem cells that are targeting cardiac repair," said Bob Atwill.

Allied is expecting to present the full data at an international scientific meeting and in peer reviewed publication in the near future.

CardioCel[®] has now been successfully implanted for the repair of congenital heart defects in Australia by Professor Tom Karl under the Authorised Prescriber Scheme. Other cardiothoracic surgeons are in the final processes of becoming authorised via the Authorised Prescriber Scheme. Allied expects to announce further updates on the early use of CardioCel[®] in patients in the near future.

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About Allied Healthcare Group's Heart Valve Reconstruction Study

The study, in a heart disease animal model, was designed to demonstrate the potential of the ADAPT[®] treated CardioCel[®] patch, versus the standard of care control, to surgically repair damaged or congenitally deformed heart valves. The model is recognised as being highly representative of the human condition associated with valvular abnormalities.

The CardioCel[®] patch was used during open heart surgery, as surgeons performed double valve leaflet reconstruction procedures. The CardioCel[®] patch material was successfully used to reconstruct the posterior leaflet of the mitral valve as well as one of the valve leaflets of the pulmonary valve. Treated autologous pericardium (native tissue) was used as the control for reconstruction of the mitral and pulmonary valves.

Eight months post-surgery, echocardiography was used to determine valve function and to detect the presence of valve calcification. Valves were retrieved and assessed for immune responses (cytotoxicity), remodeling and structural degeneration by means of microscopic evaluation of antibody markers, histological stains and molecular quantification of calcification levels.

The result highlights are:

- Endothelialisation (initial formation of an endothelial layer) of both valve surfaces, the developmental prerequisite for a normal physiological heart valve-blood interface.
- The generation of new valvular collagen on both sides of the valve reconstructions, which resembles typical native valve tissue and indicates progression to a repaired heart tissue.
- The transdifferentiation of some of the valvular interstitial cells into functional phenotypes such as new smooth muscle cells.
- Molecular examination of the extractable calcium showed 40% less in CardioCel[®] compared to the autologous control tissue.
- No echocardiographic evidence of calcification in the CardioCel[®] treatment arm.

About Allied Healthcare Group Limited

Allied Healthcare Group Limited (ASX: AHZ) is a diversified healthcare company focused on investing in and developing next generation technologies with world class partners, acquiring strategic assets to grow its product and service offerings and expanding revenues from its existing profitable medical sales and distribution business. The Company has assets from Research & Development through Clinical Development as well as Sales, Marketing and Distribution.

Allied Healthcare Group is in the process of commercializing its innovative tissue engineering technology for regenerative medicine. Allied also has major interest in developing the next generation of vaccines with a Brisbane-based research group led by Professor Ian Frazer. The vaccine programs target disease with significant global potential like herpes and Human papillomavirus.

Further information on the Company can be found on www.alliedhealthcaregroup.com.au.



Allied's Regenerative Medicine Franchise

Allied's regenerative tissue engineering technology started as a research program in in 2001 focusing on tissue engineering and regenerative medicine based around the proprietary ADAPT[®] Tissue Engineering Process (TEP). The lead program, CardioCel[®] has successfully completed a number of animal studies and a Phase II human clinical trial. CardioCel[®] is a cardiovascular patch used to repair paediatric heart deformities. These deformities range from routine "Hole in the Heart" operations to major vessel outflow tract repairs. The CardioCel[®] patch may also be used to repair leaking heart valves in paediatric patients. 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 CardioCel[®] facilitates endogenous stem cells and other cells to regenerate and repair damaged tissue.

The franchise is based on the patented ADAPT[®] Tissue Engineering Process (TEP) as a platform technology to produce implantable tissue patches for use in various soft tissue repair applications and for the production of replacement tissue heart valves. The ADAPT[®] technology is used to process animal derived tissues to produce unique implantable tissue patches that are compatible with the human body. The technology has a number of advantages over current tissue treatment processes on the market, most notably the reduction of calcification post implantation. This technology has the potential for medical professionals to use regenerative products instead of synthetic products currently used in soft tissue repair.

* Körbling & Estrov, 2003. Adult Stem Cells for Tissue Repair — A New Therapeutic Concept? NEJM Volume 349:570-582, August 7, 2003, Number 6



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