

ASX ANNOUNCEMENT

Allied's CardioCel[®] a superior platform for stem cell seeding and growth

- Study confirms CardioCel[®] superior for seeding, growing and sustaining stem cells over current tissue products
- Data supports recent regenerative nature of CardioCel[®] tissue implants
- CardioCel[®] has potential to support true tissue regeneration
- Study undertaken in collaboration with CSIRO

Brisbane, Australia, 6 February 2013

Allied Healthcare Group (ASX: AHZ) today announced the successful results of a joint study with CSIRO which found Allied's CardioCel[®] tissue patches offers superiority for stem cells survival and growth compared to the gold-standard tissues now in surgical use.

The study compared the performance of CardioCel[®] engineered tissue against glutaraldehydeprepared tissue (the control) which is widely used in cardiac repair surgery, and assessed their ability to maintain a viable population of mesenchymal stems cells (MSCs).

"These data further supports our recent announcement on tissue regeneration that CardioCel[®] implants offer in reconstructing heart valves and broadens the potential of ADAPT[®] prepared tissue to be used as scaffolds to seed and deliver stem cells for soft tissue repair," said Lee Rodne, Allied Healthcare Group Managing Director. "This is exciting as it expands the potential of our ADAPT[®] tissue to be used as a truly regenerative treatment for a number of diseases and conditions. The first product CardioCel[®] will be launched into the global market within the next 12 months."

In a recent heart model study (announced 28th of November, 2012), Allied showed that autologous tissue formed around the CardioCel[®] product, including the formation of endothelial and muscle cells. The data shows that CardioCel[®] is suitable for tissue regeneration, either via implanted stem cells or through autologous tissue regeneration. The lack of cytotoxicity and other advantageous characteristics make it a favourable bioscaffold to grow and/or deliver stem cells for cardiovascular repair.

The study results showed significantly better stem cell viability at 1 day after seeding of the CardioCel[®] tissue relative to the control tissue. Furthermore, at 7 days post seeding, virtually no MSCs survived on the control tissue; however the MSCs on the CardioCel[®] patch material were viable, healthy and appeared to be infiltrating the tissue (see Appendix).

Stem cells were found to divide and survive as viable cells on the CardioCel[®] tissue matrix over an extended period of time; whereas in the control very few stem cells remained. Staining of these cells also suggested they were producing the muscle protein F-actin. Detailed examination showed stem cells adhering to the CardioCel[®] matrix whereas the control matrix showed cells to be rounded and loosely attached (see appendix).

These striking differences are highly supportive of the continuation of the development of CardioCel[®] and other ADAPT[®] treated tissue based products as new platforms for the proliferation and delivery of stem cells (see the appendix of results below).

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The *in situ* data suggests that CardioCel[®] tissue could support seeding by endogenous stem cells allowing true regeneration of the tissue. The findings from these studies provide additional evidence to existing preliminary *in vivo* data where, in addition to the ADAPT[®] tissue showing significantly reduced calcification, it also supports cell viability and growth as evident from tissue infiltration of implanted tissues (Neethling et al 2010).

"The ability of the ADAPT[®] prepared tissues to support stem cell viability provides an additional avenue to develop the technology as a second generation approach to treat cardiac disease, further supporting our CardioCel[®] product. This also provides evidence that our regenerative tissue could be used as a biological scaffold for stem cell delivery in the treatment of other soft tissue injuries," said Bob Atwill, Allied Healthcare Group Executive and CEO of Allied's Regenerative Medicine Division.

"As well as offering advancement in the potential delivery of stem cells, these data also indicate that the CardioCel[®] tissue has regenerative potential. As we move into the next phase of our collaboration, these findings offer a number of very promising avenues to pursue," said Dr Keith McLean, the Biomedical Materials and Devices Theme Leader at CSIRO. Dr Keith McLean's research is focused on developing biomaterials for application in tissue repair, replacement and regeneration.

These studies demonstrate further positive results supporting the potential for Allied's ADAPT[®] tissue treatment technology across a range of surgical applications, with the opportunity to have a significant impact on many global markets for soft tissue repair. In addition to the initial cardiovascular suite of products, such as CardioCel[®], Allied Healthcare Group is evaluating how the ADAPT[®] platform technology can be used in pelvic floor reconstructions, hernia repairs and orthopaedics, as well as a biological scaffold to grow and deliver stem cells.

Allied plans to present the data for peer review in the near future.

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Appendix: Phase I in vitro results

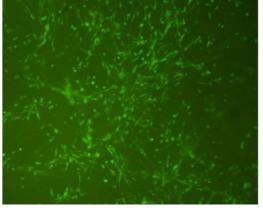
Two studies compared Allied's ADAPT[®] tissue engineered bovine pericardial tissue and bovine pericardial tissue prepared by glutaraldehyde treatment according to methods used for standard commercially available products (control) were seeded with various concentrations of mesenchymal stem cells and monitored over 7 days. Cells were stained for viability (green fluorescence) at days 1 and 7 and then the tissues were compared. The results were the same across both studies, showing superior stem cells seeding facilitation with Allied's ADAPT[®] treated tissue.

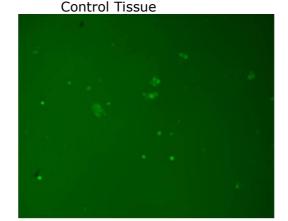
All matrices were seeded at 50,000 mesenchymal stem cells/cm² and photographed at 10x magnification (see below). In the images the bright fluorescent green spots indicate viable mesenchymal stem cells. The tissue matrix material is shown as a dull green background as observed in images of the control tissues. From Day 1 it is obvious that Allied's ADAPT[®] prepared tissue is superior to enabling stem cells to seed onto the tissue compared to the control.

DAY 1 RESULTS

Results demonstrated significantly improved survival of stem cells at day 1:

ADAPT[®] Tissue





Fluorescent green spots indicate viable mesenchymal stem cells.

DAY 7 RESULTS

Analysis at day 7 (see below) shows significantly high cell viability at day 7 on Allied's ADAPT[®] tissue whereas the control tissue shows very limited cell survival. Results clearly indicate superiority of ADAPT[®] over standard commercial tissue in reduced cytotoxicity and also the apparent ability of the cells to infiltrate the tissue matrix, as evident from fluorescent streaks (see ADAPT[®] tissue below)

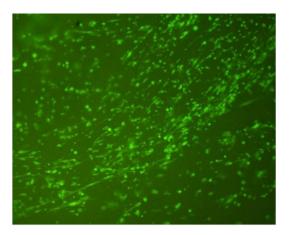


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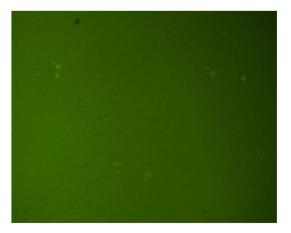
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ADAPT[®] Tissue



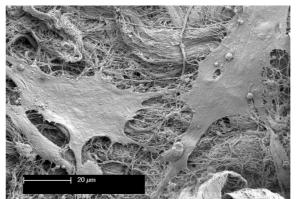
Control Tissue



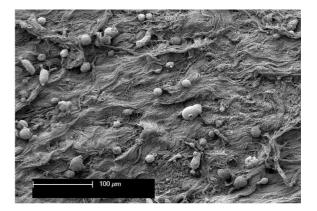
Fluorescent green spots indicate viable mesenchymal stem cells.

Scanning electron microscopy results

Scanning electron micrograph $\mathsf{ADAPT}^{\texttt{®}}$ tissue tissue



Scanning electron micrograph control



 $\mathsf{ADAPT}^{\$}$ prepared tissue shows cells on surface that are flattened and adherent, control tissue shows rounded cells poorly adherent to surface

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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 commercialising 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 programmes target disease with significant global potential like Herpes and Human Papilloma virus.

Further information on the Company can be found on <u>www.alliedhealthcaregroup.com.au</u>.

Allied's Regenerative Medicine Division

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. The lead programme 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[®] has been shown to allow tissue regeneration once implanted. Some researchers postulate that stem cells play an active role in tissue regenerate and repair damaged tissue.

The division is based on the patented ADAPT[®] Tissue Engineering Process 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, <u>August 7, 2003</u>, <image001.png>Number 6

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