

### **ASX ANNOUNCEMENT**

#### CLINICAL TRIAL EXTENSION STUDY UPDATE - STILL NO CALCIFICATION

- Four year follow up data from the Phase II study
- Patients continue to show no calcification of implanted tissue
- CardioCel® on track for first approval mid-year

## Brisbane, Australia, 6th March 2013

Allied Healthcare Group (ASX: AHZ) today announced its CardioCel<sup>®</sup> implants continue to show no calcification four years after implantation in patients. Patients involved in an ongoing Phase II extension study were assessed four years after their congenital heart defect was repaired using CardioCel<sup>®</sup>. The assessment found no sign of calcium build-up at the site of repair, a result also seen when the same patients were reviewed at three years post-surgery. The Company will continue to monitor these patients.

"Four years without calcification when typically it is seen within six months post-surgery with existing marketed products is a significant result for us," said Managing Director Lee Rodne. "This provides additional positive data on CardioCel® and its potential to prevent repeated surgeries for patients with heart disease."

Currently Allied Healthcare Group is progressing CardioCel® for CE Mark approval in Europe as part of its global launch of the product. The Company also expects to file a 510(k) marketing approval submission with the FDA in the near future. CardioCel® is currently being used in Australia at the Mater hospital in Brisbane under the Authorised Prescriber Scheme (APS) with other major hospitals expected to gain access through APS in the near future.

Congenital heart disease is a leading cause of mortality in infants globally. In Australia 6 children are born with congenital heart disease every day and over 40,000 born each year in the US.

In total there are 25 patients being followed in the extension study with 7 beyond 4 years and another 6 over 3 years all without calcification. The company anticipates providing additional updates in the future.

"CardioCel® with its anti-calcification profile, regenerative properties and ease of handling has many advantages over existing tissue products used in surgery and offers surgeons, and patients, the real opportunity for reduced interventions in their long-term management," said Bob Atwill, Group Executive and CEO, Regenerative Medicine Division.

Studies have shown CardioCel® has unique properties making it suited to use by surgeons as a regenerative cardiac repair tissue, as well as delivering key benefits to patients compared to existing surgical approaches. Videos on CardioCel® can be viewed at: <a href="http://www.alliedhealthcaregroup.com.au/video">http://www.alliedhealthcaregroup.com.au/video</a>

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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 www.alliedhealthcaregroup.com.au.

### **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® 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.



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The division is based on the patented ADAPT<sup>®</sup> 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<sup>®</sup> 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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