

**ASX ANNOUNCEMENT**

**First patients receive Allied's CardioCel® to treat congenital heart defects**

- Australian-developed cardiovascular tissue patch (CardioCel®) used in open heart surgery for the first time
- Studies show CardioCel® may eliminate risk of needing revision surgery later in life
- CardioCel® offers next generation biocompatibility, demonstrating improved integration into the surrounding heart tissue, whilst reducing key adverse outcomes such as tissue hardening compared to conventional approaches
- First used by Professor Tom Karl (Brisbane's Mater Hospital) and more surgeons now in process of becoming authorised for the use of CardioCel®

**Brisbane, Australia, 18 October 2012**

Australian biomedical company Allied Healthcare Group (ASX: AHZ) announced today the first use of its cardiovascular tissue patch CardioCel® to surgically repair Congenital Heart Defects (CHD) in infants.

The surgery, performed at Brisbane's Mater Hospital this week, represents the first use of CardioCel® outside of a clinical trial. The Therapeutic Goods Administration (TGA) last month authorised CardioCel® use for surgical repair of CHD under an Authorised Prescriber Scheme, allowing the authorised cardiothoracic surgeon to use the heart patches to treat their patients prior to full marketing approval.

"The use of CardioCel® is expected to add significant long term value to our existing surgical practice of repairing CHD and is expected to allow our patients to live a 'normal' life, free of implanted tissue related complications," said Professor Tom Karl, who performed the surgery.

"The authorised prescriber approval provides an exciting opportunity for our patients to benefit from this new technology immediately," he said.

Ten years of preclinical and clinical studies have shown CardioCel® patches have no evidence of toxic cell damage (cytotoxicity) or build-up of hard tissue at the site (calcification) for one to three years post-surgery.

Lee Rodne, Allied Healthcare Group Managing Director, said that CardioCel® provides a biocompatible scaffold for native tissue repair and also retains tensile strength, thereby addressing key problems associated with existing tissue matrix products.

"The global medical community has been searching for tissue that doesn't cause the patient's own heart tissue to react negatively," said Lee Rodne, Allied Healthcare Group Managing Director.



“CardioCel<sup>®</sup> represents a major breakthrough in this endeavour and it has the potential to alter treatment for a range of tissue related heart repairs globally”.

Bob Atwill, Allied Healthcare Group Executive and CEO of the regenerative medicine franchise said CardioCel’s ultimate market was global.

“The first use of CardioCel<sup>®</sup> patches took place in Australia and was delivered by an Australian company. This is an important new technology for the global market, and has a high potential of making a significant difference to CHD patients’ lives as well as to their families”.

“Other key Australian surgeons are in the final processes of becoming authorised for the use of CardioCel<sup>®</sup> via the Authorised Prescriber Scheme”. Congenital heart defects are a major cause of death in infants globally. In Australia, CHD prevalence has been recorded at around 8 cases per 1,000 live births. More CHD patients are now living till adulthood, requiring lifelong solutions for their congenital heart defects.

Allied Healthcare is in the process of seeking full TGA approval of CardioCel<sup>®</sup> and will be lodging for FDA approval in the US at the end of this year, or in early 2013. Mr Atwill said an application for a CE mark to allow CardioCel<sup>®</sup> entry to European and other markets is also “well underway”.

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### **About CardioCel®**

CardioCel® is the lead program from Allied's regenerative medicine franchise and has successfully completed over 20 preclinical studies and a Phase II human clinical trial with data out to 3 years. CardioCel® is a cardiovascular tissue patch for use in repairing heart deformities. These deformities range from routine "Hole in the Heart" operations to major vessel outflow tract repairs and heart valve reconstructions.

### **Allied's regenerative medicine franchise**

Allied's regenerative tissue engineering technology started as a research program in 2001 focusing on tissue engineering and regenerative medicine based around the proprietary ADAPT® Tissue Engineering Process (TEP).

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.

### **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 programs 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](http://www.alliedhealthcaregroup.com.au).



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