

**ASX ANNOUNCEMENT**

**ALLIED LODGES 510(K) WITH FDA FOR CARDIOCEL® MARKETING APPROVAL**

- **CardioCel® progresses towards global marketing approval**
- **510(K) submission lodged in the U.S.**
- **CardioCel® on track for initial approval in 2013**

**Brisbane, Australia, 2nd April 2013**

Allied Healthcare Group (ASX: AHZ) today announced that on the 29<sup>th</sup> of March, US time, the Company lodged its Premarket Notification 510(k) Submission for CardioCel® in the United States (U.S). The FDA 510(K) submission is a major step in Allied's strategy to gain marketing approval for CardioCel® in the U.S.

CardioCel® is a cardiovascular tissue patch used to repair heart deformities including repairing and reconstructing heart valves. CardioCel® has unique properties making it suited for use by surgeons as a regenerative cardiac repair tissue, as well as delivering key benefits to patients compared to existing surgical approaches.

"The U.S. is the largest global market for regenerative medicine and this is therefore a key milestone for Allied. Our U.S. opinion leaders are very supportive of our application and key centers are ready to use CardioCel® when approved by the FDA," said Allied Healthcare Group Managing Director Mr Lee Rodne.

This 510(K) submission is part of a global strategy to gain marketing approval for CardioCel®. The Company is anticipating the initial approval in Europe with its CE Mark mid-2013. To date the Company has received strong support from key opinion leaders due to the benefits the product offers both patient and surgeon and has already been authorised for early access via the Authorised Prescriber Scheme in Australia.

"This is a significant milestone for us. Gaining approval gives us commercial entry into markets, as well as offering patients and surgeons a superior product with key differences and advantages from products currently used.

"CardioCel's® potential to prevent additional revision surgeries for patients later in life will also be of enormous benefit to the patient community," said Lee Rodne.

Recent data shows that four years after CardioCel® has been implanted there has been no calcification of the tissue, a major issue with existing tissue products that in many cases results in the need for additional surgeries.

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.

"This is the culmination of a great deal of hard work from the Allied Regenerative Medicine Team getting the 510(k) submission in on time and within budget," said Bob Atwill, Allied Group Executive and CEO, Regenerative Medicine Division.

Videos on CardioCel® can be viewed at: <http://www.alliedhealthcaregroup.com.au/video>



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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](http://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<sup>®</sup> Tissue Engineering Process. The lead programme CardioCel<sup>®</sup> has successfully completed a number of animal studies and a Phase II human clinical trial. CardioCel<sup>®</sup> 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<sup>®</sup> patch may also be used to repair leaking heart valves in paediatric patients. CardioCel<sup>®</sup> 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<sup>®</sup> 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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