

ASX ANNOUNCEMENT

Allied making progress towards CE Mark approval for CardioCel®

- **Receives ISO certification for CardioCel**
- **Anticipates CE Mark by mid-2013**

Brisbane, Australia, 13 February 2013

Allied Healthcare Group (ASX: AHZ) today announced an update of its regulatory progress for European CE Mark approval for CardioCel®, its lead regenerative tissue product for the repair and treatment of Congenital Heart Defects (CHD). Allied has progressed well with the process to date, including receiving its ISO 13485 certification, a key part of the CE approval process.

Allied has now successfully completed stage 1 and 2 audits resulting in the Company receiving its ISO certification and expects to receive European marketing approval for CardioCel® by mid-2013.

"Obtaining ISO 13485 is a critical step along the path to obtaining a CE Mark, which opens up the European Union market as well as many other markets around the world to grow significant revenue from our lead regenerative tissue product starting in 2013. This will also assist in Allied obtaining its Health Canada Medical Device License for CardioCel®," said Lee Rodne, Allied Healthcare Group Managing Director.

Certification against ISO 13485 indicates that Allied has successfully implemented a Quality Management System that conforms to the International Organization for Standardisation (ISO) standards for medical devices. ISO 13485 is an internationally recognised standard defining requirements for the design, development and manufacturing of safe medical devices.

Allied has also recently successfully undergone a Quality Management System audit by the Therapeutic Goods Administration (TGA) as part of the Conformity Assessment Review of CardioCel®.

"Obtaining ISO 13485 for our Quality Management System and having undergone a TGA audit are significant achievements as we progress through the CardioCel® regulatory processes," said Bob Atwill, Allied Healthcare Group Executive and CEO of the Regenerative Medicine Division.

CardioCel® has the potential to have a major impact on many global markets for repairing and treating cardiovascular defects. It shows clear advantages over existing products and addresses a number of major issues in this space faced by surgeons, mainly the prevention of calcification, its regenerative tissue benefits and ease of use.

In addition to CardioCel® and the initial cardiovascular suite of products, Allied is also evaluating other applications for its ADAPT® tissue engineering platform technology, such as its use in pelvic floor reconstructions, hernia repairs, orthopaedics and as a biological scaffold to grow and deliver stem cells.



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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® 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, August 7, 2003, Number 6



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