

#### ASX ANNOUNCEMENT

# 5``]YXBg'7UfX]c7Y`® authorised for early use in patients

- TGA gives authorisation to CardioCel® tissue patch under Authorised Prescriber Scheme
- CardioCel® continues to gain support of key cardiothoracic surgeons
- Additional authorisations expected in the near future

### Brisbane, Australia, 26 September 2012

Allied Healthcare Group (ASX: AHZ) announced today the Therapeutic Goods Administration (TGA) has authorised the use of CardioCel®, a cardiovascular tissue patch, for reconstruction & repair of Congenital Heart Defects (CHD) under an Authorised Prescriber Scheme. The Authorised Prescriber Scheme allows cardiothoracic surgeons to apply to use CardioCel® in patients prior to marketing approval under a special access program once the product has been reviewed by the hospital.

The approval for use is now in place following an application by Professor Tom Karl at the Mater Hospital in Brisbane. Professor Karl is now able to use CardioCel® to repair and reconstruct congenital heart defects in patients. Congenital heart defects remain a major cause of death in infants globally.

"The granting of TGA Authorised Prescriber status is an exciting step forward for CardioCel®. It demonstrates the excellent support we are receiving from key surgeons," said Lee Rodne, Allied Healthcare Group Managing Director. "Crucially it brings our ADAPT®-treated tissue to a major patient group in need in Australia. CardioCel® can now be accessed by the Mater Hospital for life saving heart surgery."

This authorisation is a major milestone for Allied's ADAPT® technology, and an important recognition of the benefits the Company's initial product CardioCel® is expected to bring to heart repair.

"The Allied regenerative medicine team is very excited about pre-approval authorisation for use," said Bob Atwill Allied Healthcare Group Executive and CEO of the regenerative medicine franchise. "A number of other key cardiothoracic surgeons are also in process of making similar applications to the TGA as a result of CardioCel®'s preclinical and clinical data showing its effectiveness in treating congenital heart defects."

Allied's ADAPT® tissue engineering technology has already shown significant anti-cytotoxic and anti-calcification properties in multiple preclinical studies and a Phase II clinical study. These properties, that help prevent cell damage and the hardening of tissue after surgery, demonstrate CardioCel®'s significant benefits over existing tissues currently available to surgeons. The use of CardioCel® is expected to reduce or eliminate the need for repeat surgeries in paediatric patients, potentially a very significant impact on patient's lives.

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CardioCel®'s use in CHD patients fills a high unmet clinical need and because of this the Company is expecting additional hospitals to be successful in their Authorised Prescriber applications to the TGA in the coming months. The ADAPT® platform technology, used in the production of CardioCel®, has the potential to have a major impact on global markets for many soft tissue repair and reconstruction surgical procedures. It shows clear numerous 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. The safety and efficacy profile is also supported by 36 month study data in CHD patients.

In addition to 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 commercializing its innovative tissue engineering technology for regenerative medicine. Allied also has a 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 Papillomavirus.

Further information on the Company can be found on <a href="www.alliedhealthcaregroup.com.au">www.alliedhealthcaregroup.com.au</a>.



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## 5``]YXthy fY[YbYfUh]j Ya YX]W]bY 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 lead program has successfully completed a number of animal studies and a Phase II human clinical trial for its lead product CardioCel®. CardioCel® is a cardiovascular patch used to repair heart deformities. These deformities range from routine "Hole in the Heart" operations to major vessel outflow tract repairs and heart valve reconstructions.

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.

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