

ASX ANNOUNCEMENT

# Allied Healthcare announces positive 2 & 3 year Phase II follow up data from CardioCel<sup>®</sup> Clinical Trial

# Patients showed no significant calcification over 3 years No other adverse issues with the CardioCel patches

## Brisbane, Australia, 5th April 2012

Allied Healthcare Group (ASX: AHZ) announced today its tissue engineering and regenerative medicine division Celxcel has released positive 36-month post Phase II human clinical trial follow-up results of paediatric patients who received ADAPT<sup>®</sup> tissue engineered CardioCel<sup>®</sup> patches during various corrective cardiac surgical procedures.

CardioCel<sup>®</sup> is a collagenous-based bioprosthetic device, made of tissue derived from bovine pericardium and treated with Celxcel's ADAPT<sup>®</sup> Tissue Engineering Process.

The follow up program followed selected patients to evaluate over a 3-year period. To date 14 patients have been followed up after 2 years and 5 patients have reached 3-year follow up points. All patients were free of patch-related complications or adverse events. Echocardiographic (heart ultrasound) results showed intact haemodynamics (blood flow) with no evidence of significant calcification of the CardioCel<sup>®</sup> patch at the 24 and 36-month evaluation.

"The follow up data further supports the data for the Celxcel technology, in particular the prevention of calcium build up in tissue post implantation," stated Allied Healthcare Group MD Lee Rodne. "This is a major market differentiator for products using the technology and provides major benefit for patients longer term."

In May, 2008, 30 patients (Age range; 3months - 14 years) were implanted with the ADAPT<sup>®</sup> engineered CardioCel<sup>®</sup> patches. The study included paediatric patients diagnosed with congenital heart disease that required a tissue patch for corrective surgical repairs during major open-heart surgery

The follow-up and evaluation of these patients has been under the supervision of the Principal Investigator and the paediatric cardiology team at the Universitas Hospital, Bloemfontein, South Africa. The follow up patients were provided a cardiac clinical evaluation, a full blood count, and an echocardiographic (Heart ultrasound) study to evaluate haemodynamic compatibility, evidence of calcification and the general efficacy of the CardioCel<sup>®</sup> patch.

"Following these encouraging results we will be actively reviewing all patients in the Phase II study in order to get valuable additional long-term data for these paediatric CHD patients," said Bob Atwill CEO of Celxcel.

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The CardioCel<sup>®</sup> product is based on proprietary technology known as the ADAPT<sup>®</sup> Tissue Engineering Process. This uses animal derived tissues to produce products that are compatible with the human body. The ADAPT<sup>®</sup> process produces tissue that more closely mimics human tissue and is expected to open up the potential for medical professionals to replace synthetic products currently used in soft tissue repair.

In addition to cardiovascular, pelvic floor reconstructions and hernia repair applications, Celxcel is also evaluating how the process can be used in orthopaedics and as a biological scaffold to grow and deliver stem cells. Celxcel is currently pursuing regulatory marketing approvals in a number of countries for the CardioCel technology.

## For more information, please contact:

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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 and is a major investor in Brisbane based Coridon Pty Ltd, led by Professor Ian Frazer developing next generation vaccines for global markets.

Further information on the Company can be found on <u>www.alliedhealthcaregroup.com.au</u>.

### **About Celxcel**

Celxcel, a regenerative tissue engineering technology company founded in 2001 that has completed a Phase II human clinical trial for its lead product CardioCel<sup>®</sup>. 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.

Celxcel uses its patented ADAPT<sup>®</sup> 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.

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