

## **ASX ANNOUNCEMENT**

### **Allied Healthcare announces a global regulatory strategy update for the CardioCel® cardiovascular patch.**

#### **Brisbane, Australia, 5th March 2012**

The board of Allied Healthcare Group (ASX:AHZ) would like to announce that its tissue engineering and regenerative medicine division Celxcel continues to progress its regulatory strategy for bringing its products to market in major global markets, which it anticipates will accelerate the approval process for the ADAPT® technology.

"Celxcel is confident that market authorisations will be granted in 2012 and 2013 to market CardioCel and other ADAPT® (Celxcel's proprietary tissue engineering process) treated products" stated Lee Rodne Allied Healthcare Group Managing Director.

"With a focus on delivering shareholder returns as well as therapeutic value, our strategy is to get products to market as soon as we can, while at the same time looking at broader applications for future market opportunity."

#### **Australian regulatory approval submission**

The Company has received confirmation from the Therapeutic Goods Administration (TGA) that its CardioCel® cardiovascular patch has been successful in the pre-assessment of the submission and is now moving forward in the conformity assessment evaluation process for the Australian market. Discussions with opinion leaders on our Advisory Board regarding use of CardioCel® prior to TGA approval in clinical trials and other pre-market access routes are also advancing. Should these approaches be progressed, further updates will be made to the market at that time. Based on the current progress and interaction, the Company is anticipating an approval for the program at the end of 2012.

#### **European regulatory approval submission**

The Company has started discussions with SGS, an international third party assessment organisation who can act as Celxcel's Notified Body for European CE Marking. SGS is also able to assist in obtaining Canadian Marketing Authorisation, in addition to other countries such as Taiwan and Hong Kong. Celxcel is investigating which other markets will be opened up outside of Europe by obtaining CE Mark. The Company anticipates providing shareholders an update on the submission in the first half of 2012.



### **US regulatory approval submission**

The Company is also currently planning filing for US approval. The approach to the Food and Drug Administration (FDA) application is the key to gaining marketing approval for the US market. The Company is currently investigating, in conjunction with a global Contract Research Organisation (CRO) & regulatory consulting group, the best approach for US submission. The Company anticipates providing shareholders with an update once the initial assessment is completed.

Allied Healthcare Group Executive and Celxcel CEO Bob Atwill said, "The ADAPT®-treated patch has over the past decade been successfully tested in a number of in-vitro, in-vivo models and a Phase II clinical trial setting to assess the durability, biocompatibility and calcification potential of the implant. We are pleased to be on the threshold of the first product from this platform technology being launched into the cardiovascular marketplace."

In addition to the initial cardiovascular products, Celxcel is also evaluating how the process can be used in pelvic floor reconstructions, hernia repair, orthopaedics and as a biological scaffold to grow and deliver stem cells.

### **For more information, please contact:**

Dr Julian Chick, Chief Operating Officer Allied Healthcare Group Tel: +61 417 137 291  
Bob Atwill, Allied Healthcare Group Executive and Celxcel CEO Tel: +61 448 778 880

Media:

Paul Dekkers  
Buchan Consulting  
+61 2 9237 2800  
[pdekkers@buchanwe.com.au](mailto:pdekkers@buchanwe.com.au)

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



### About Celxcel

Celxcel, a regenerative tissue engineering technology company founded in 2001 focusing on tissue engineering and regenerative medicine based around the proprietary ADAPT® Tissue Engineering Process (TEP). Celxcel's 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 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.

Celxcel uses its 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.

