

Allied Healthcare's CardioCel trial shows efficacy

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Singapore: Australia-based Allied Healthcare's ongoing phase II extension study for CardioCel, its lead regenerative tissue product, showed continued evidence of the long-term benefits of CardioCel for patients, including no sign of calcification at the site of repair.

As part of the study, five patients have been monitored over a five-year period post-surgery, with the results showing no signs of calcification in these patients. In addition six patients have progressed beyond four years, and eight beyond three years, all showing no signs of calcification in ongoing post-surgical monitoring. Patients will continue to be monitored.

"These results show the potential of CardioCel in not only providing a regenerative tissue for the repair and reconstruction of congenital heart disease and cardiovascular defects, but also the long term benefit for patients in preventing calcification of tissue," said Mr Lee Rodne, CEO, Allied Healthcare Group.

The original phase II study met its primary and secondary endpoints of 30-day survival post-surgery. Around 20 patients have continued to be monitored in an extension study to explore the longer term benefits of CardioCel for these patients. Patients in the study were aged from two months-to-14 years.

"This data will be used to support ongoing launch activities in Europe by highlighting the long-term benefits of the product. We are expecting initial sales of CardioCel in Europe in the coming months," said Mr Rodne. Allied recently received approval of CardioCel in Europe and anticipates approval of the product in the US in 2014.