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Allied Healthcare gets CE mark for CardioCel in EU

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Singapore: Australia-based Allied Healthcare has received CE mark approval for its regenerative product, CardioCel, allowing the company to launch and market the product in Europe. Allied had recently received its ISO 13485 certification, a key part of the CE approval process.

Allied Healthcare CEO Mr Lee Rodne said, "The CE mark approval for our lead regenerative product CardioCel is a key milestone for Allied. As we continue to roll-out CardioCel in different markets, we can look forward to increased revenue streams and we expect to see a significant lift in company revenue over the coming years."

The company will now look to take advantage of this CE mark to launch and start selling the product throughout Europe. The CE mark for CardioCel allows for the repair and reconstruction of heart defects including treating congenital heart disease and repairing heart valves in both children and adults.

In addition to commercial and scientific validation, the approval of CardioCel technology in Europe offers a platform to launch additional cardiovascular products, as well as regenerative tissue products for the repair and reconstruction of other defects and diseases.

"CardioCel's approval in Europe provides the surgeons with an important addition to their treatment in the repair of cardiac defects, and offers children and adults suffering from cardiac defects and disease a promising new technology that displays strong levels of regeneration and long term benefits," stated Mr Rodne.

Allied Healthcare Group is expecting sales of CardioCel in Europe to begin in the fourth quarter of the current calendar year. CardioCel offers key benefits for patients and surgeons including showing strong levels of regeneration of self-tissue without needing external stem cells or growth factors and no cytotoxicity at the site of repair, thereby reducing the issue of calcification which can often lead patients to have repeat surgeries. Allied Healthcare is also pursuing approval for CardioCel in the US and anticipates approval in 2014.