ortho·cell
advancing tissue repair & regeneration

Early positive results for CelGro™ in human tendon study

- Orthocell reports positive safety and tolerability results from interim review of clinical study using CelGro™ to treat full thickness tendon tears in the shoulder
- Study was designed to demonstrate that CelGro™ can be used as an augment to surgically repair the rotator cuff tendon, is safe and tolerable, and can improve tissue healing and integration of the repair
- Study performed in collaboration with three of leading orthopaedic surgeons in Australia, the University of Western Australia and the St John of God hospital group

Perth, Australia; 16th June 2016: Regenerative medicine company Orthocell is pleased to announce positive initial safety and tolerability results for its CelGro™ collagen-based medical device, in a pilot clinical study examining its use to augment the repair of full thickness tears of the rotator cuff tendon in the shoulder.

An interim review at 42 days post operation for the first three patients to receive CelGro™ showed no complications and demonstrated that the scaffold is safe and has been well tolerated with no inflammatory reactions or complications noted.

Orthocell Managing Director Paul Anderson said: "This initial assessment is very positive and represents an important step forward in the development of CelGro™. Finding a cell and tissue-friendly scaffold that is also capable of load sharing to support tissue regeneration has been a challenge that has not been adequately addressed by other scaffolds currently available."

There are more than 370,000 rotator cuff surgeries carried out in US every year. Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015 revealed that large rotator cuff repairs regularly tear again, at a rate of up to 57% in a series of 500 patients studied. Previous research showed that 20%-90% of rotator cuff surgical repairs tore again.

The CelGro™ SMRT Graft™ collagen scaffold aims to reduce this re-tear rate by providing a more cell friendly environment to improve tissue healing and quality, and integration and stabilisation of the repair. This represents a significant near-term market opportunity for CelGro™, with applications for regulatory registration in Europe planned for 2016.

The company believes CelGro represents a breakthrough in regenerative medicine that has been developed and manufactured in Australia. CelGro™ has been shown to significantly improve tissue in-growth and repair and has been developed for use in surgical applications such as tendon, bone and cartilage repair and to guide and support the restructuring of damaged tissue in the body. Pipeline opportunities are also in development for applications within the general surgical and Urogynecological specialities, amongst others.

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About Orthocell Limited

Orthocell is a commercial-stage, regenerative medicine company focused on regenerating mobility for patients and our ageing population by developing products for a variety of tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-approved stem cell therapies Autologous Tenocyte Implantation (Ortho-ATI™) and Autologous Chondrocyte Implantation (Ortho-ACI™), which aim to regenerate damaged tendon and cartilage tissue. The Company's other major product is Celgro™, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications and is being readied for first regulatory approvals.