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Orthocell receives approval for human tendon study using Celgro™

- Human ethics approval granted for a clinical study using Celgro™ SMRT Graft™ collagen scaffold for the treatment and augmentation of rotator cuff tendon surgeries of the shoulder

- Study aims to demonstrate that Celgro™ can be used as an augment to rotator cuff surgery and is a safe and effective treatment

- Performed in collaboration with leading Australian orthopaedic surgeons, Saint John of God Hospital Group and the University of Western Australia

Perth, Australia; 16th December 2015 Regenerative medicine company Orthocell has been granted ethical approval by St John of God Hospital Group for a clinical study examining the safety and effectiveness of its Celgro™ SMRT Graft™ collagen scaffold, used as an augment to the surgical repair of the rotator cuff tendon in the shoulder.

Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015 found that large rotator cuff repairs tear again at a rate of 57% in a series of 500 patients. Previous research showed that 20%-90% of rotator cuff repairs tore again. The Celgro™ SMRT Graft™ collagen scaffold aims to reduce this re-tear rate by improving mechanical stabilisation and providing a more cell friendly environment to improve healing.

Orthocell received ethics approval to conduct the study from the Australia-wide St John of God Hospital Group. The study will involve 30 patients and be conducted in Perth, Western Australia, by some of Australia's leading orthopaedic surgeons.

Orthocell Managing Director Paul Anderson said: "This is an exciting new phase in the development of Celgro™ and its applications as an augment to soft tissue reconstruction such as tendons. The rotator cuff can be a problematic tendon to heal so it is hoped that Celgro™ will improve surgical outcomes."

Celgro™ is unique from other collagen scaffolds currently used in surgical procedures and has been shown to actively promote and improve tissue ingrowth and repair. Celgro™ has been developed for use in surgical applications such as tendon repair, dental applications and restructuring of damaged soft tissue in the body.

Principal investigator Professor Allan Wang said: "Celgro™ SMRT Graft™ is a novel biological device that has the potential to augment rotator cuff surgeries and improve outcomes for patients with larger tendon tears. The unique properties of Celgro™ SMRT Graft™ may provide a more effective repair than currently available scaffolds."

Celgro™ is a bio-device developed and manufactured in Australia to address unmet clinical needs in the general surgical and orthopaedic soft tissue repair market around the

world. The global orthopaedic soft tissue repair market was worth approximately $US7 billion in 2013 and is expected to be worth more than $US10 billion by 2020.

The clinical study is due to begin in the first quarter of calendar 2016.

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About Orthocell Limited

Orthocell is a commercial-stage, regenerative medicine company focused on 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.

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