

Orthocell receives approval for human hip study using Celgro™

- Human ethics approval granted for a clinical study using Celgro™ SMRT Graft™ collagen scaffold for the treatment and augmentation of articular cartilage surgeries of the hip
- Study aims to demonstrate that Celgro™ can be used as an augment to hip cartilage surgery and is a safe and tolerable treatment
- Performed in collaboration with leading Australian orthopaedic surgeon and the St Vincent Hospital, Melbourne

Perth, Australia; 04 May 2016: Regenerative medicine company Orthocell Limited (“the Company”) has been granted ethical approval by St Vincent Hospital, Melbourne for a clinical study using its Celgro™ SMRT Graft™ collagen scaffold.

The primary objective of the study is to demonstrate the safety and tolerability of Celgro™ when used as the collagen matrix in treatment for osteochondral defects in the hip. This treatment is known as Autologous Matrix Induced Chondrocyte (AMIC) and is an enhanced version of the original micro fracture technique, in which a type I/III collagen matrix is placed over the cartilage defect to stabilise the fragile bone marrow cell infiltrate and provide infrastructure for tissue repair and regeneration (1).

Orthocell received ethics approval to conduct the study from the Human Resource Ethics Committee at St Vincent Hospital. The study will involve 25 patients and is to be conducted at St Vincent Hospital.

Orthocell Managing Director Paul Anderson said: “This is an exciting new phase in the development of Celgro™ and its application as an augment to cartilage repair and further demonstrates the applicability of Celgro™ across a number of important clinical indications.”

Celgro™ has unique characteristics of cell compatibility, tensile strength and has been shown to actively promote and guide quality tissue ingrowth and repair. Orthocell is currently undertaking other clinical studies using Celgro™ to augment repair of the rotator cuff tendon within the shoulder and as an augment to guide bone regeneration within the jaw.

Principal investigator for the newly approved study, Dr John O’Donnell said: “Celgro™ SMRT Graft™ is a novel biological device that has the potential to augment AMIC treatment for osteochondral defects within the hip. The unique properties of Celgro™ SMRT Graft™ may provide a more effective repair than currently available treatments.”

Celgro™ is a biological medical device developed and manufactured in Australia to address unmet clinical needs in the orthopaedic and general surgical soft tissue repair market. 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 second quarter of calendar 2016.

(1) Fontana A. A Novel Technique for Treating Cartilage Defects in the Hip: A Fully Arthroscopic Approach to Using Autologous Matrix-Induced Chondrogenesis. Arthrosc Tech. Elsevier Inc.;2012;1(1):e63–8.

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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.

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