Orthocell receives ethics approval for pilot Ortho-ATI® tendon study

- Orthocell receives ethics committee approval for clinical study comparing Orthocell's minimally invasive tendon regeneration therapy (Ortho-ATI®) to corticosteroid injection
- Study aims to demonstrate the safety and feasibility of Ortho-ATI® for treatment of rotator cuff tendinopathy and tear
- Performed in collaboration with DePuy Synthes Products, Inc., part of the Johnson & Johnson Family of Companies

Perth, Australia; 1 May 2017: Regenerative medicine company Orthocell Limited today announced that it has received ethics approval to conduct a Ortho-ATI® tendon study titled: "Defining a randomised, controlled study of Ortho-ATI® vs corticosteroid injection for treatment of rotator cuff tendinopathy and tear."

Rotator cuff tendinopathy and tear (shoulder pain) is a common and difficult injury to treat with more than 50% of adults over 50 years of age affected. Rotator cuff disease leads to considerable disability, reduced quality of life, and absenteeism from work and is a burden on healthcare resources. The burden on the healthcare system is expected to increase as the population ages.

The objective of this study is to assess the safety and feasibility of Autologous Tenocyte Injection (Ortho-ATI®) compared to corticosteroid injection in the treatment of rotator cuff tendinopathy and tear.

Patient recruitment will commence shortly and will enroll 30 patients randomised to receive either Ortho-ATI® or corticosteroids. Patients in the trial will have failed previous conservative treatment options, including physiotherapy and other injection therapies. The trial will be led by Professor Allan Wang, current President of the Australian Elbow and Shoulder Society, in conjunction with Professor Ming Hao Zheng, Division of Surgery, School of Medicine at the University of Western Australia.

Orthocell Managing Director Paul Anderson said: "Demonstrating the efficacy of Ortho-ATI® for rotator cuff tendinopathy is an important element of our product development strategy. We expect results to show Ortho-ATI® is a durable, curative and cost effective treatment for degenerate shoulder injuries. Our collaboration with DePuy Synthes enables global development of the technology." The collaboration was facilitated by Johnson & Johnson Innovation.

In studies conducted by Orthocell to date, Ortho-ATI® has been shown to be a cost effective long-term and durable, non-surgical solution for difficult to treat tendon pathology. Ortho-ATI® is available in Australia, New Zealand, and Hong Kong for patients who have failed conservative treatment options such as corticosteroid injections and exercise programs and have ongoing symptoms.

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About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-licensed 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.