Orthocell receives ethics approval for pivotal Ortho-ATI™ tendon study

- Orthocell receives ethics committee approval for clinical trial comparing Orthocell's minimally invasive tendon regeneration therapy versus surgery
- Study to enrol patients suffering from chronic and severe treatment resistant Lateral Epicondylitis (tennis elbow)
- Two of Australia's leading elbow surgeons will conduct the trial commencing in Q3 calendar 2016, enrolling 25 patients per treatment arm

Perth, Australia; 12 July 2016: Regenerative medicine company Orthocell Limited today announced that it has received ethics approval to conduct a study comparing surgery for severe tennis elbow to Orthocell's minimally invasive cell therapy Ortho-ATI™ injection.

The study will be conducted by two of Australia's leading elbow surgeons with ethics approval received from The Avenue hospital in Melbourne, which is part of the Ramsey Health Care group and follows publication of Orthocell's positive pilot study results announced in April 2015 in the prestigious American Journal of Sports Medicine.

Patient recruitment will commence in Q3 2016 and the study is designed to show that a single non-invasive treatment of Ortho-ATI™ is superior or equivalent to the more costly and invasive surgical intervention for the repair of severe, treatment resistant Lateral Epicondylitis. This program will support the continued demonstration of clinical efficacy and the cost effectiveness of Ortho-ATI™ as a minimally invasive injectable treatment for resistant tendon injuries of the elbow.

Orthocell Managing Director Paul Anderson said: "Demonstrating equivalence or superiority of Ortho-ATI™ to the standard surgical approach which, for tennis elbow, has a mixed success rates is an important element of our growth strategy. We expect a repeat of the results that showed Ortho-ATI™ was a durable, curative and cost effective treatment for degenerate tennis elbow injuries."

Trial co-investigator and Orthocell Chief Scientific Officer Professor Ming Hao Zheng said: "As the population ages and degenerate tendon conditions become much more prevalent, doctors and patients are seeking cost effective, minimally invasive and evidenced based treatments to alleviate symptoms that affect their mobility and quality of life. This study is an important step toward validating Ortho-ATI™ as a viable alternative to surgery."

The US, Europe and Japan markets for tennis elbow treatment is estimated to be worth US$ 700 million in 2015 by Transparency Market Research.

For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited, Managing Director

P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Gavin Lower
Buchan Consulting

P: +61 3 8866 1215
M: +61 414 796 726
E: glower@buchanwe.com.au

Investor Relations

Ben Walsh
Buchan Consulting

P: + 61 468 422 865
E: bwalsh@buchanwe.com.au

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.