Recruitment complete - Ortho-ATI® shoulder tendon study

- **Patient recruitment completed** for clinical trial comparing Orthocell's tendon regeneration therapy (Ortho-ATI®) to corticosteroids
- Trial undertaken **in collaboration with DePuy Synthes Products, Inc.,** part of the Johnson & Johnson Medical Devices Companies
- **Trial aims to assess the effectiveness of Ortho-ATI®** for the treatment of rotator cuff tendinopathy and tear, compared to corticosteroid injection

Perth, Australia; 30 June 2020: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce recruitment to the Ortho-ATI® shoulder tendon study in collaboration with DePuy Synthes Products, part of the Johnson & Johnson Medical Devices Companies ("Sponsor"), is completed.

Orthocell Managing Director, Paul Anderson, said: "We are delighted to complete the patient recruitment phase of this highly focused randomised controlled trial ("RCT"), designed to assess the effectiveness of Autologous Tenocyte Injection (Ortho-ATI®) as a treatment to a difficult clinical problem with limited alternatives."

The trial is led by Clinical Professor Allan Wang (former President of the Australian Elbow and Shoulder Society), Dr Jeff Hughes (current President of the Australian Elbow and Shoulder Society), Dr Jane Fitzpatrick, and Professor Ming Hao Zheng at the University of Western Australia (UWA).

To ensure effectiveness of Ortho-ATI® or corticosteroids were not masked by prior treatments or other medical conditions, patients were excluded from enrolling in the trial if they presented with any of the sixteen (16) exclusion criteria, including previous treatment injections in the prior three months; previous shoulder surgery or significant pathology of affected shoulder (eg inflammatory joint disease); or bilateral shoulder pathology. Whilst the very detailed exclusion criteria caused delays to the anticipated recruitment timeframes, it is consistent with best practice and is not reflective of the significant patient population that is normally suitable for treatment with Ortho-ATI®.

Ortho-ATI® can be used in both pre-surgical and post-surgical applications and is at the forefront of a large and increasing market opportunity, estimated to be worth >US$7.7bn[1] and growing. In studies conducted by Orthocell to date, Ortho-ATI® has been shown to be a cost effective long-term, non-surgical solution for difficult to treat tendons including the rotator cuff, elbow, gluteal, patellar and achilles.

Rotator cuff tendinopathy and tear (which manifests as severe shoulder pain) is a common and often difficult injury to treat and affects more than 50% of adults over 50 years of age. Rotator cuff injuries may lead to considerable disability, reduced quality of life, and absenteeism from work, and are a

[1] US, Japanese, European and Australian markets

significant burden on healthcare resources. This burden is expected to increase as the population ages, and as a result, new treatments are required that address the underlying pathology of the injury, not just the symptoms.

About Ortho-ATI®

Ortho-ATI® is a world leading breakthrough in regenerative medicine – a novel, cell therapy developed to treat chronic tendon injuries (tendinopathy / tendonitis). Treating physicians and insurers are constantly seeking advances in new treatments that are safe, effective and cost efficient.

Ortho-ATI® addresses these demands by enabling the accelerated regeneration of injured tendons, directly addressing the underlying cause of injury, replenishing degenerative tissue with healthy mature tendon cells (known as tenocytes). The treatment has been shown to support patients in their return to recreational activities, the workplace and competitive sports. Ortho-ATI® has extensive clinical validation with published clinical data up to 4.5 years post treatment in leading peer-reviewed journals (e.g. American Journal Sports Medicine), clearly demonstrating durability and efficacy as the leading tendon regeneration treatment.

Ortho-ATI® is available in Australia, New Zealand, and Hong Kong for patients who have failed conservative treatment options such as exercise programs, corticosteroid and platelet rich plasma injections.

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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 soft tissue injuries. Orthocell's portfolio of products include CelGro® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro® and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro® is being readied for first approval in the US and AUS. The Company's other

major focus is TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.