Ortho-ATI® shoulder tendon study database lock

- **The pivotal Ortho-ATI® shoulder tendon study database has been locked and the data submitted for analysis**
- **Reporting of top line results on track for Q4, 2021**
- **Ortho-ATI® shoulder tendon study is the first randomised cellular therapy study completed for this indication globally**
- **There are currently no proven long-term, non-surgical solutions to repair chronic shoulder tendon injuries**
- **Ortho-ATI® is well positioned to become the first FDA approved injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries**

Perth, Australia; 15 November 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce that the Autologous Tenocyte Injection (Ortho-ATI®) rotator cuff tendon study ('RC Study') database has been locked, indicating that the data has been signed off/verified by the clinical investigators and cannot be altered. The data has been submitted for analysis and the Company is on track for reporting top line results in Q4, 2021.

A global first in the treatment of tendon injuries

The RC Study was designed to assess the effectiveness of Ortho-ATI®, compared to corticosteroids, as a non-surgical treatment to a difficult clinical problem with limited treatment options. Should the Ortho-ATI® shoulder tendon study meet its objectives, it will be the first randomised cellular therapy study successfully completed for this indication anywhere in the world. This also places Orthocell in a strong position to progress its US commercialisation strategy to deliver the first injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries.[1]

Orthocell Managing Director, Paul Anderson, said: *"*This is an important development milestone for Ortho-ATI® and the Company and I am delighted to have reached this pivotal stage of the study."

Shortcomings of current treatment options for shoulder tendon injuries

Currently, there are no proven long-term non-surgical solutions to repair chronic shoulder tendon injuries. Initial, conservative treatment options consist of rest, physical therapy, anti-inflammatory drugs (NSAIDs), and injectables (corticosteroids or platelet rich plasma - PRP). While these interventions may provide short-term pain relief, they do not repair the underlying pathology of chronic tendon degeneration and the risk of re-injury, or the likelihood of progressing to a full-thickness tendon tear, which is significant. Treatment failure of conservative therapies affects up to three quarters of all patients.[2]

The only remaining option if conservative treatments fail - is surgery. Surgery is expensive (approx US$25,500),[3] requires additional rehabilitation with physiotherapy (approx. US$3,000) and can take 6 months to regain full use of the shoulder. Additionally, surgery is not always effective in resolving the problem, with re-tear rates reported between 20-27%.[4] A more cost effective, reliable and less intrusive treatment for shoulder pain will provide significant health and economic benefits.

---

[1] A thorough search, conducted by the Company, of published literature and key international (US, EU & UK, AU & WHO) clinical trial registries confirmed there are no completed unpublished or published RCT's assessing the effectiveness of an autologous cell therapy for the treatment of chronic tendon injuries in the shoulder.

[2] Itoi E. Rotator cuff tear: physical examination and conservative treatment. J Orthop Sci. 2013 Mar;18(2):197-204

[3] https://www.newchoicehealth.com/arthroscopic-shoulder-surgery/cost Accessed 27 Aug 2021

[4] https://www.hopkinsmedicine.org/orthopaedic-surgery/specialty-areas/shoulder/treatments-procedures/failed-rotator-cuff-repairs.html Accessed 27 AUG 2021

US addressable market

Initial market sizing undertaken by Orthocell suggests that Ortho-ATI® could be applicable to approximately 470,000 rotator cuff patients per year in the US alone,[5] which equates to a market opportunity of approximately US$2.8b[6]. Ongoing work by Orthocell aims to also assess the savings to the health system that may be delivered by Ortho-ATI® when accounting for more effective pain relief and return of function, return to work and avoidance of surgical costs. 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.

Next Steps

The Company remains on track to report the RC Study data in Q4, 2021. The Company will provide further updates in relation to the market opportunity for Ortho-ATI®, the regulatory strategy to be pursued to enable rapid approval by FDA and also the study design to facilitate the first global approval of a cell therapy for tendon injuries.

About Ortho-ATI®

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 at different anatomical sites, including the rotator cuff, elbow, gluteal, patellar and achilles (ankle) tendons. 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. Ortho-ATI® replenishes degenerative tendon 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.

Accessing Ortho-ATI®

Ortho-ATI® is available in Australia, New Zealand, and Hong Kong, via the Special Access Scheme, for patients who have failed conservative treatment options such as exercise programs, corticosteroid and platelet rich plasma injections. Under SAS approval, doctors can prescribe use of therapeutic goods prior to regulatory approval if they can justify that the product has significant advantages for their patient over existing approved products or where there are no approved products currently available.

Release authorised by Paul Anderson, Managing Director
Orthocell Ltd.
For more information, please contact:

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
H^CK Director
P: +61 423 139 163
E: haley@hck.digital

[5] Estimate based on 5 million patients per year presenting with shoulder tendinopathy, 18% failure rate of conservative therapies (899,694 patients) and 460,000 rotator cuff surgeries performed in the United States in 2019

[6] Internal Orthocell modelling based on published epidemiology data and assuming target pricing for a subset of the rotator cuff injury segment.

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®, a collagen medical device which facilitates tissue repair and healing in a variety of dental, nerve and orthopaedic, reconstructive applications. Orthocell recently received FDA 510(k) approval for Striate+, the first application of the CelGro® platform for dental GBR applications. Striate+ is also approved in Australia (ARTG) and Europe (CE Mark) for the same. The Company's other major products are the cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is moving forward with Ortho-ATI® 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.