

# **Orthocell's Ortho-ATI® shows 87.5% success rate**

- 87.5% respondents satisfied with treatment outcomes in Orthocell's annual quality study using Ortho-ATI<sup>®</sup> cell therapy for treatment of chronic tendon injuries in the shoulder
- 74.3% patient satisfaction in all patient groups including, elbow, hip, knee and ankle
- **Strong correlation to clinical study outcomes** published in leading scientific journals, including the American Journal of Sports Medicine
- **Annual quality study** captures patient feedback/outcomes for reduction of pain, functional improvement and overall satisfaction, in patients suffering from chronic tendon injuries

**Perth, Australia; 9<sup>th</sup> July 2020:** Regenerative medicine company <u>Orthocell Limited</u> (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the results from its 2019 Annual Quality Study ("AQS"), which shows a 87.5% patient satisfaction rating using Ortho-ATI® cell therapy for the treatment of chronic tendon injuries of the shoulder and a 74.3% patient satisfaction rating for all indications combined.

**Orthocell Managing Director, Paul Anderson, said:** "The 2019 Annual Quality Study has provided further evidence that Ortho-ATI<sup>®</sup> is a breakthrough technology that significantly improves patients' lives returning them to normal function at home and at work, pain free. This is important real world evidence that adds to our growing body of supporting data."

As part of Orthocell's commitment to its continuous delivery of high quality regenerative medicine products, the Company administers an Annual Quality Study to capture patient feedback following treatment of chronic tendon injuries with Orthocell's Ortho-ATI® cellular therapy. The 2019 study indicated 87.5% of shoulder patients were satisfied with how Ortho-ATI® relieved symptoms (i.e. chronic pain) and improved ability to perform everyday activities at home and at work.

# **Ortho-ATI patient, Daniel Kerr**

A well-known face in AFL, Daniel Kerr is best known for playing 220 games for the West Coast Eagles between 2001 and 2013. At the age of 28, he suffered a complete hamstring rupture, which doctor's described as a 'career ending injury'. After exhausting traditional surgical and non-surgical treatments, he was treated with Ortho-ATI<sup>®</sup>. This is his story. <u>https://www.orthocell.com.au/tendon-regeneration</u>

# Annual quality study results and historical trends

Orthocell has conducted the AQS four (4) times since 2015 receiving one hundred and sixty one (161) responses in total. It is an important measure of patient satisfaction with the Ortho-ATI<sup>®</sup> cell therapy and compliments Orthocell's formal clinical studies that have been published in leading scientific journals, including the American Journal of Sports Medicine, reporting similar positive outcomes.

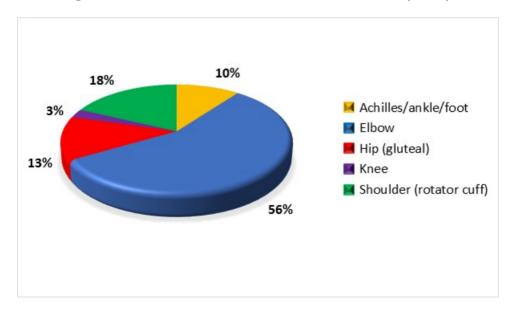




Thirty nine (39) patients responded to the 2019 AQS (21 females / 18 males; mean age of 52 years old). Summary results of the 2019 AQS and trends since 2015 included:



- **87.5% satisfaction in patients who received** Ortho-ATI<sup>®</sup> tendon repair treatment, in the shoulder, **in the four AQS surveys** conducted between 2015 and 2019
- **74.2% satisfaction in patients who received** Ortho-ATI® tendon repair treatment **in the four AQS surveys** conducted between 2015 and 2019
- **2019 AQS included treatment of six (6) different anatomical locations** (tendons) including Elbow (56%), Shoulder (18%), Hip (13%), Knee (3%) Achilles/ankle/foot (10%) refer to Figure 1



#### Figure 1: Ortho-ATI<sup>®</sup> treatment sites 2019 Annual Quality Study

### About Ortho-ATI®

Ortho-ATI<sup>®</sup> is a world leading breakthrough in regenerative medicine – a novel, cell therapy developed to treat chronic degenerative tendon injuries (tendinopathy / tendonitis). Tendinopathy places a significant financial burden on the public health care system which is expected to increase as the population ages. Treating physicians and insurers are constantly seeking advances in new treatments that are safe, effective and cost efficient.





Ortho-ATI<sup>®</sup> 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 allows patients to return to recreational activities, the workplace and competitive sports. Ortho-ATI<sup>®</sup> 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.

Chronic tendon pain is a highly prevalent condition. For example, tennis elbow (elbow pain) affects 1-3% of the general population. Ortho-ATI<sup>®</sup> is at the forefront of a large and growing market opportunity where the addressable market is estimated to be >US\$7.7bn1 and growing.

Ortho-ATI<sup>®</sup> is available to patients in Australia, New Zealand, Singapore and Hong Kong.

### **Release authorised by:**

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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<sup>®</sup> 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<sup>®</sup> and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro<sup>®</sup> 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<sup>®</sup>) and Autologous Chondrocyte Implantation (Ortho-ACI<sup>®</sup>), which aim to regenerate damaged tendon and cartilage tissue.



<sup>&</sup>lt;sup>1</sup> US, Japanese, European and Australian markets



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 <u>www.orthocell.com.au</u> or follow us on Twitter **@OrthocellItd** and LinkedIn <u>www.linkedin.com/company/orthocell-Itd</u>

#### **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 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.

