OrthoATI™ tendon clinical study success

- **Study results show that OrthoATI™ is significantly more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear**
- **95% of participants** at 12 months **post OrthoATI™ treatment** reported a level of function of the treated shoulder consistent with a **successful outcome** after having received an average of 4 failed conservative treatments including physiotherapy and steroid injections
- **OrthoATI™** patients experienced almost complete **resolution of pain by month 1 post-treatment** which was sustained over the assessment period
- Participants receiving a **steroid injection had no meaningful improvement in function, and only a transient improvement in pain** at month 3 before returning to pre-treatment levels
- **64% of steroid participants withdrew early** from the study due to treatment failure. Of these early withdrawals, **86% requested and received OrthoATI™ treatment** due to ongoing pain and loss of shoulder function
- There are currently **no proven long-term non-surgical solutions to treat chronic shoulder tendon injuries**
- **OrthoATI™** is well positioned to become **the first FDA-approved injectable cell therapy in orthopaedics** for the treatment of chronic tendon injuries.

Perth, Australia; 08 December 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce statistically significant results from its randomised, multicentre, controlled rotator cuff tendon clinical study ('RC Study'). The data confirmed that the study achieved its goals, demonstrating that OrthoATI™ is a safe and effective treatment for patients suffering from rotator cuff tendinopathy with intrasubstance tendon tear compared directly to the standard of care (steroid injections).

In light of these results, the Company is accelerating its US commercialisation plans with technology transfer, FDA engagement and commercial preparation activities for a randomized controlled study under FDA supervision.

Orthocell Managing Director, Paul Anderson, said: *"*We are absolutely delighted with the study results for this challenging and debilitating condition which clearly demonstrates that OrthoATI™ is more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear. This is an important development milestone for OrthoATI™ and the Company.

We are now in a very strong position to progress our US commercialisation strategy to deliver the first injectable cell therapy in orthopaedics that truly addresses the cause of degeneration and returns patients to full use of their chronically damaged tendons."

Rotator cuff tears lead to considerable pain and disability, and conservative treatment options, (such as steroid injections and pain medications which may provide short-term pain relief), do not address the chronic underlying pathology of tendon degeneration. Patients with an intrasubstance tendon tear cannot be surgically repaired if conservative treatment fails. OrthoATI™ represents a potential breakthrough treatment option to resolve pain and return functional mobility for this debilitating condition. **Watch video here.**

RC Study participants suffered from pain and loss of shoulder function for almost 2 years (average of 23.5 months in the RC Study) and received an average of 4 failed treatments (including physiotherapy, corticosteroid or Platelet Rich Plasma or 'PRP' injections), prior to enrolment in the study. Following treatment,

assessment of pain and shoulder function showed that the OrthoATI™ group had significantly better results compared to the steroid group at all post-treatment time points. **See attached presentation for further detail on the RC Study and the statistically significant results here.**

Leading Australian orthopaedic surgeon and clinical trial lead, clinical professor Allan Wang of UWA, commented: "The rotator cuff trial results are very encouraging. OrthoATI™ consistently improved pain and shoulder function in patients suffering chronic shoulder symptoms from rotator cuff tendinopathy and tear. Patients are pleased to have a nonsurgical treatment option available, with reduced recovery times before returning to their work and recreational activity."

Summary of results

- The RC Study demonstrated that OrthoATI™ is significantly more effective than a steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear.
- Patients in the OrthoATI™ group experienced almost complete resolution of pain by month 1 post-treatment (VAS score less than 3), while patients in the steroid group experienced a transient improvement in pain, which peaked at month 3 then returned to pre-treatment levels;
- The OrthoATI™ group experienced significant improvement in shoulder function between 6 and 12 months post-treatment. The steroid group experienced no meaningful improvement in shoulder function at any time point;
- The mean ASES scores were significantly better in the OrthoATI™ group compared to the steroid group at all post treatment time points: month 1 (p=0.006), month 3 (p=0.026), month 6 (p=0.012) and month 12 (p=<0.001);
- None of the participants in the OrthoATI™ group withdrew from the study due to treatment failure, but 64% (7 of 11) of steroid participants withdrew before month 12 due to steroid treatment failure; 6 of 7 (86%) of those participants requested and received OrthoATI™ treatment after withdrawing from the study;
- Both study treatments were well tolerated, and no safety concerns for OrthoATI™ were identified;

Clinical trial patient, Paul Speering commented: *"The steroid treatment didn't work and since the OrthoATI™ treatment, as a drug free and fully drug tested athlete, I have become both a Masters National Powerlifting Champion and the Oceanias Masters Powerlifting Champion, and hold all four State Records in my age and weight category. I was so fortunate to be involved in this study, and I wish that more people would be able to take advantage of the treatment. It truly has been life changing for me."*

US addressable market

Initial market sizing undertaken by Orthocell suggests that Ortho-ATI® could be applicable to >480,000 rotator cuff patients per year in the US alone, which equates to a market opportunity of approximately US$4-5 billion[1]. Ongoing work by Orthocell aims to also assess the savings to the health system that may be delivered by OrthoATI® 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, not only in treating rotator cuff injuries, but many other tendon injuries and is at the forefront of a significant and increasing market opportunity.

Next Steps

The Orthocell team was responsible for the initial development of a similar cell therapy product for the regeneration of cartilage (known as MACI) which is now being commercialised by US company Vericel, which

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

generates more than $120 million in sales for one target joint in the body and has a market capitalisation of approximately $2 billion.

Orthocell is in a strong position to advance its US commercialisation strategy to deliver the first injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries.[2] The results of this study demonstrate that OrthoATI™ is more effective than steroid injections for treatment of rotator cuff tendinopathy with intrasubstance tendon tear. As a consequence, the Company is now accelerating its US plans with technology transfer, FDA engagement and commercial preparation activities underway to prepare OrthoATI™ for a randomized controlled study under FDA supervision. A number of key US based consultants have joined the team including:

- Matt Kemp – former head of commercialisation for cell therapy company Dendreon who has unique experience in positioning and marketing biologic drugs in orthopedics with Biomet and Allergan;
- Brandon Miller – a co-founder of Rebellion solutions and senior marketing and sales executive with Biomet;
- Dr Lara Silverman – an expert in autologous cell therapies who until recently led the FDA regulated clinical development and manufacturing activities for a spinal disc regeneration product with Discgenics; and
- Leslie Wise – a director of Orthocell and specialist in reimbursement and market entry strategy development and execution with Biomet, Angiodynamics and BMS.

Clinical trial investigators

The RC study has been 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 (University of Western Australia and co-founder of Orthocell).

Detailed study description

The RC Study was a randomized, multicenter, open-label study designed to assess OrthoATI™, in comparison to steroids (standard of care), as an emerging treatment for patients with rotator cuff tendinopathy with intrasubstance tendon tear. A total of 30 participants verified by MRI with symptom duration >6 months, and who had previously received physiotherapy AND one or more corticosteroid injections were treated. Participants were randomized to receive an ultrasound guided injection of tendon derived cells that had been cultured from a sample drawn from each patient (OrthoATI™; 19 patients), or an ultrasound guided injection into the subacromial space of Celestone Chronodose (steroid; 11 patients). The characteristics of both groups were comparable with respect to age, gender, mean duration and severity of symptoms. Participants had received an average 4 failed prior treatments (including physiotherapy, steroid injection or PRP injection) and had experienced pain and loss of function on average of 23.5 months prior to study participation.

Assessment results

Assessments of shoulder function, pain, quality of life, and tendon structure were performed using validated outcome measures before treatment, and for up to 12 months post-treatment.

[2] 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.

Visual Analogue Scale Pain Assessment

The Visual Analogue Scale (VAS) pain score rates pain from 0 (no pain) to 10 (worst pain). Participants were asked to rate their pain at its worst, at rest, lifting a heavy object, performing a repetitive task, and at night. An overall pain score for each participant visit was calculated by taking the mean of reported scores for individual ratings. A change in VAS pain score of 1.4 points (from pre-treatment score) represents the smallest change in score that patients would perceive as a meaningful improvement. A VAS pain score of 3 or less is considered by patients as a "successful outcome".

OrthoATI™ participant group

Patients receiving OrthoATI™ experienced significant and sustained reduction in pain after treatment.

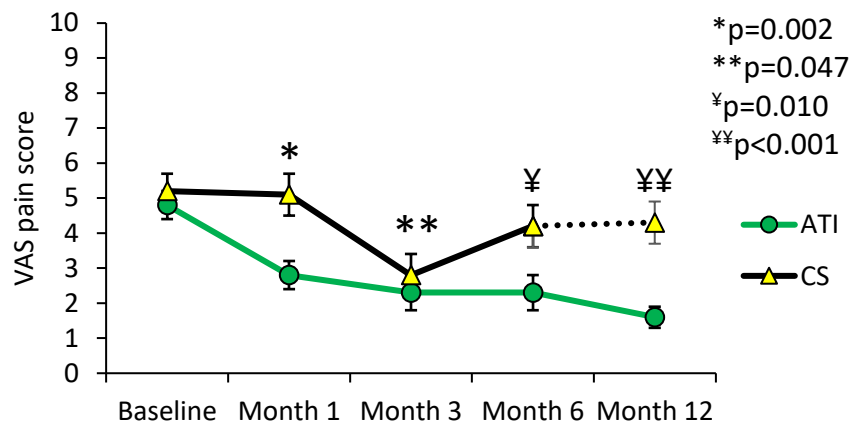
- Patients experienced meaningful improvement in pain as early as 1-month post-treatment;
- The average VAS pain score reduced 3.2 points, from 4.8 pre-treatment to 1.6 at 12 months post-treatment (Figure 1). The reduction in VAS pain score was continuous and sustained over the assessment period; and
- At 6 months post-treatment, 67% (12 of 18) of participants reported a VAS pain score of 3 or less ("successful outcome"), improving to 84% (16 of 19) of participants at 12 months post-treatment.

Corticosteroid participant group

Patients receiving Corticosteroid experienced a transient improvement in pain which was not sustained, peaking at 3 months then returning to pain levels experienced pre-treatment.

- The average VAS pain score reduced 0.9 points from 5.2 pre-treatment to 4.3 at 12 months post-treatment (Figure 1). The average VAS pain score improved to 2.8 at month 3, but worsened to 4.2 by 6 months post-treatment;
- The mean improvement in VAS pain score from pre-treatment to 6 months (1.0) was below the threshold for meaningful improvement; and
- Only 27% (3 of 11) of participants achieved a VAS pain score of 3 or less ("successful outcome") 6 months post-treatment.

Figure 1 – Visual Analogue Scale Pain Assessment (VAS Pain)



Mean overall VAS pain score at baseline (pre-treatment) and at 1,3, 6 and 12 months post-treatment with ATI or CS.

Dashed line indicates that there was a significant drop-out in the CS group at month 6, with only 4 patients remaining by month 12

*/¥ - statistically significant differences between treatment groups

Assessment of Shoulder Disability and Function

The American Shoulder and Elbow Surgeons Shoulder Assessment (ASES) score is a standardized method for assessing outcomes of shoulder and elbow surgery. It comprises assessments of pain and function with a combined ASES/Shoulder Function score ranging from 0-100, with a higher score indicating better outcomes. A change in ASES score of 12 points (from pre-treatment score) represents the smallest change in score that patients would perceive as a meaningful improvement. An ASES score of 78.6 or more is considered by patients as a "successful outcome".

OrthoATI™ participant group

Patients receiving OrthoATI™ experienced a significant and sustained improvement in pain and return of shoulder function after treatment.

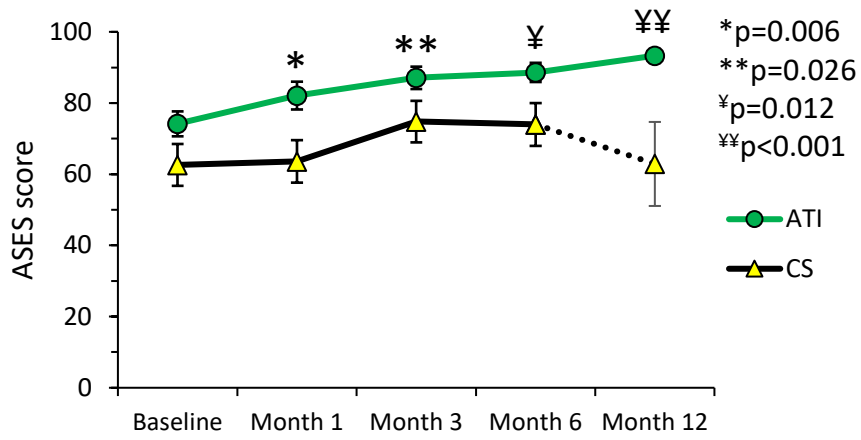
- The average ASES score improved 19.1 points from 74.2 pre-treatment to 93.3 at 12 months post-treatment (Figure 2). The improvement in ASES score was continuous and sustained over the assessment period;
- The mean improvement in ASES score pre-treatment to 6 (14.4) and 12 (19.1) months post-treatment was greater than the smallest change (12) that would be considered as a meaningful improvement; and
- At 6 months post-treatment, 72% (13 of 18) of participants reported an ASES score of 78.6 or better (successful outcome), improving to 95% (18 of 19) of participants at 12 months post-treatment, i.e achieved a level of shoulder function consistent with a successful outcome

Corticosteroid participant group

Patients receiving Corticosteroid did not experience a significant or sustained improvement in pain and shoulder function after treatment.

- The average ASES score improved 0.3 points from 62.6 pre-treatment to 62.9 at 12 months post-treatment (Figure 2);
- The mean ASES score remained essentially unchanged from 62.6 pre-treatment to 63.6 at 1 month post-treatment, increasing at 3 months post-treatment to 74.8 and then declining at 6 months post-treatment to 74.0 (Figure 2);
- The mean change in ASES score was too low to be considered a meaningful improvement;
- There was not enough data to accurately assess change from pre-treatment to 12 months post treatment because 7 of 11 (64%) participants withdrew from the study prior to month 12. Reason for withdrawal was due to worsening symptoms or lack of improvement. The remaining 4 (of 11) participants who completed month 12 recorded an average ASES score of 62.9, also below the threshold considered to be successful outcome; and
- 6 of 7 (86%) participants who withdrew from the study requested and received OrthoATI™ treatment after withdrawing from the study.

Figure 2 - American Shoulder and Elbow Surgeons Assessment (ASES)



Mean ASES score at baseline and at 1,3, 6 and 12 months after treatment with ATI or CS.

Dashed line indicates that there was a significant drop-out in the CS group at month 6 resulting in 4 patients remaining in month 12

*/¥ - statistically significant differences between treatment groups

MRI data

Analysis of MRI data showed that there appeared to be no connection between tendon tear size and clinical outcomes after treatment. This is consistent with published literature indicating that tendon abnormalities observed on MRI do not necessarily relate to the presence of clinically significant symptoms.

About OrthoATI®

OrthoATI®is an autologous cell therapy comprising tendon derived cells for the repair and relief of chronic tendon injuries. In studies conducted by Orthocell to date, OrthoATI® 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. Treating physicians and insurers are constantly seeking advances in new treatments that are safe, effective and cost efficient. OrthoATI® 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 derived cells. 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 OrthoATI®

OrthoATI® 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 authorized by Paul Anderson, Managing Director
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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®, 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 (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is accelerating the development of Ortho-ATI® in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a Phase 2b clinical study.

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.

OrthoATI™

Advanced cellular therapy to directly address the cause of chronic tendon injury

OrthoATI™ Overview

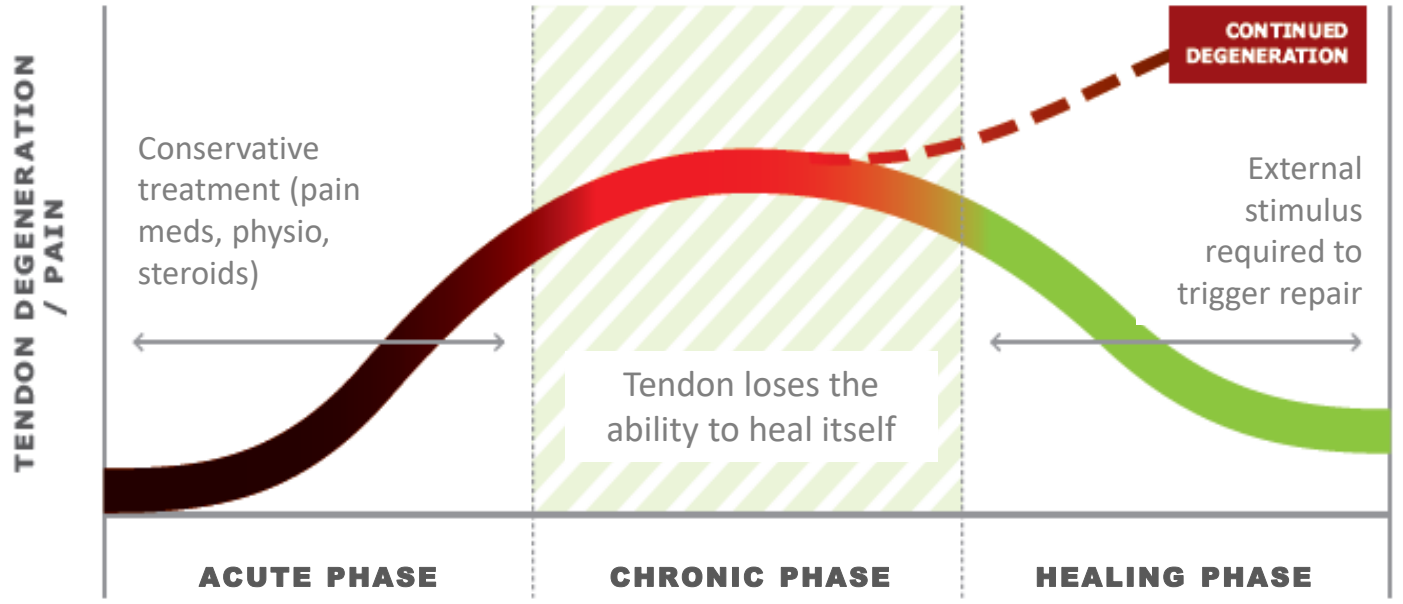
Successful multi-centre, randomised, active controlled study now accelerates US clinical program

- OrthoATI™ is a biological treatment for tendon injuries, delivering the specific cells that build and repair tendon, directly back into the injury site
- OrthoATI™ is the only disease modifying cell therapy for treatment of chronic tendon injuries (tendinopathy) – enables recovery of function and reduces pain
- Demonstrated safety and efficacy with patients ranging from professional athletes to everyday workers – more than 800 patients treated to date
- Orthocell founders successfully developed *MACI* for global approval (cartilage cell repair technology – now a US$2B company (Vericel) generating ~US$120M p.a)
- Applicable to over 480,000 rotator cuff tendon patients each year in the US alone - US$4-5 billion addressable market
- Successfully completed a randomised study comparing OrthoATI™ to steroids

Chronic tendinopathy and OrthoATI™

Chronic tendon injury is a common and painful disorder affecting millions of people every year with no effective, non-surgical treatments currently available

- Significantly reduces a patient's ability to work, exercise and perform routine daily activities
- Multi-billion-dollar burden on global health care systems
- The most commonly used non-surgical therapeutic option (i.e., steroids) *can damage* the tendon long term
- High demand for new treatments that are safe, effective, minimally invasive and cost efficient



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The problems with steroid injections

Ineffective long-term and can cause biological damage to tendon

Temporarily masks symptoms

Cartilage damage

Death of nearby bone

Joint infection

Nerve damage

MAYO CLINIC

US Reimbursement for steroid declining rapidly

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https://www.mayoclinic.org/tests-procedures/cortisone-shots/about/pac-20384794

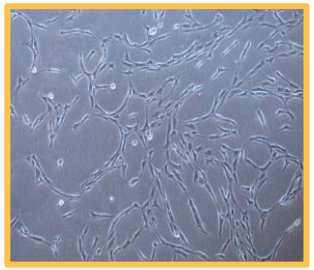
OrthoATI™ - first disease modifying non-surgical solution for RC repair

Two stage, minimally invasive procedure

1. **Biopsy procedure**

Healthy tendon cells removed via minimally invasive procedure

2. **Tendon derived cell cultivation**



Healthy cells grown at Orthocell's laboratory

3. **Tendon derived cell implantation**

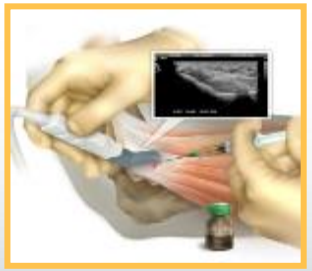


Image guided injection of OrthoATI™ healthy cells

4-5 week end-to-end process

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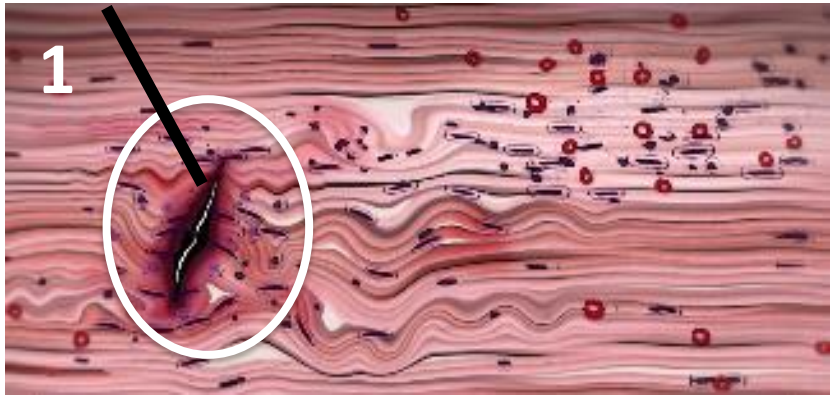
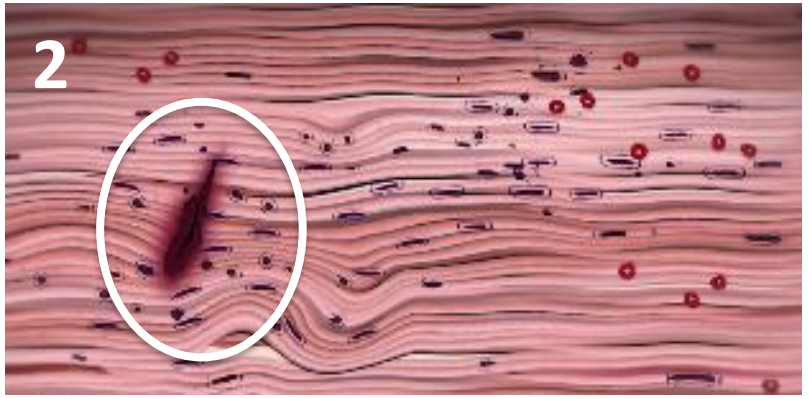
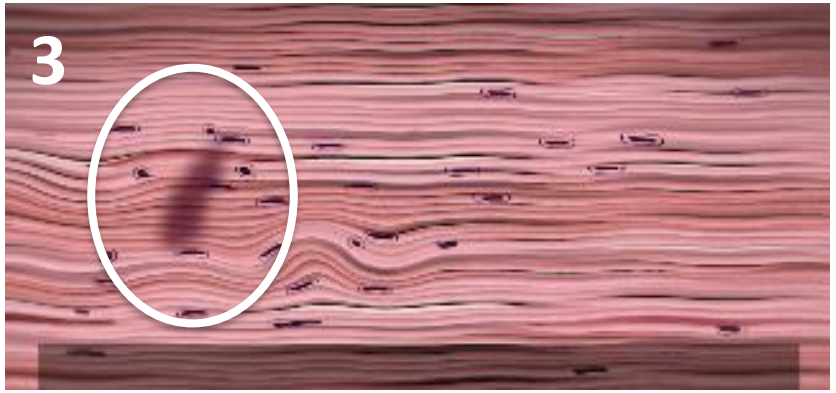
How OrthoATI™ works



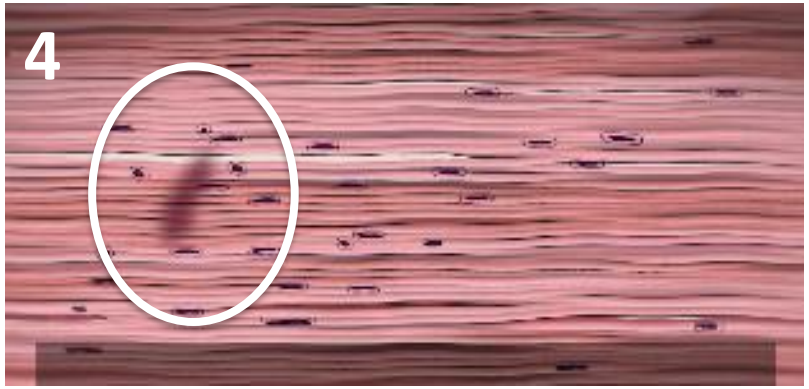
Tendon derived cells (TDCs) injected into defect in target tendon



TDCs begin to produce tendon matrix, including Type 1 collagen



TDCs recruit other native cells to help repair tendon and align fibres



Treatment reduces pain and improves function

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advancing tissue repair & regeneration

Click here to watch video

Randomised study of OrthoATI™

Open label randomised study to assess efficacy and safety of OrthoATI™ vs steroid injection for treatment of partial intrasubstance rotator cuff tear and tendinopathy

Key eligibility criteria:

- Symptom duration > 6 months
- Tendinopathy with intrasubstance tendon tear (verified by MRI)
- Previously received physical therapy and at least one corticosteroid injection
- Prior shoulder surgery excluded
- At least 3 months since last corticosteroid or other injectable treatment

Participant population:

- 19 participants received OrthoATI™ injection and 11 participants received corticosteroid injection
- Mean age - 50.5 years (SD 8.5, range 30.3- 63.4)
- Gender - 10 female and 20 male participants
- Mean duration of functional limitations and pain, almost 2 years (23.5 months) (SD 18.3. range 7-60)

OrthoATI™ study results

OrthoATI™ is significantly more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear

- Patients in OrthoATI™ group experienced almost complete resolution of pain by month 1 post-treatment (VAS score less than 3), while patients in the steroid group experienced a transient improvement in pain, which peaked at month 3 then returned to pre-treatment levels
- The OrthoATI™ group experienced significant improvement in shoulder functional between 6 and 12 months post-treatment. The steroid group experienced no meaningful improvement in shoulder functional at any time point
- Mean ASES scores were significantly better in the OrthoATI™ group compared to the steroid group at all post treatment time points: month 1 (p=0.006), month 3 (p=0.026), month 6 (p=0.012) and month 12 (p=<0.001)
- None of the participants in the OrthoATI™ group withdrew from the study due to treatment failure, but 64% (7 of 11) of steroid participants withdrew before month 12, due to steroid treatment failure; 6 of 7 (86%) of those participants requested and received OrthoATI™ treatment after withdrawing from the study
- Both study treatments were well tolerated, and no safety concerns relating to OrthoATI™ were identified

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Statistically significant VAS Pain Score outcomes

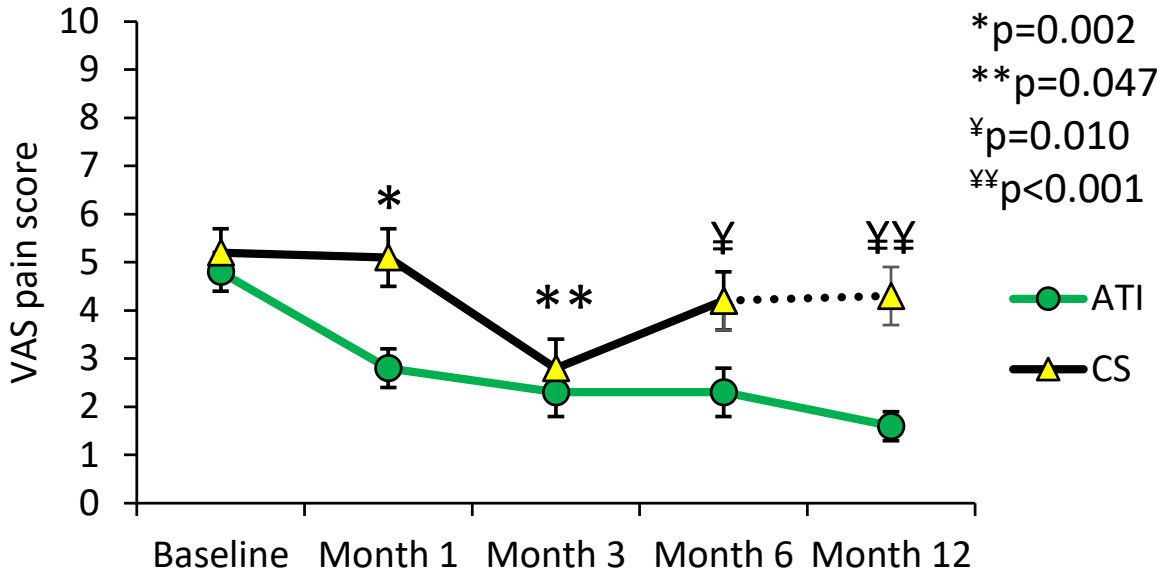
Patients randomised to OrthoATI™ experienced a significant and sustained reduction in pain after treatment

OrthoATI™

- Meaningful improvement in pain as early as 1-month post-treatment
- Average VAS pain score reduced 3.2 points at 12 months post-treatment and was sustained over the assessment period
- At 6 months post-treatment, 67% of participants reported a VAS pain score of 3 or less ("successful outcome"), improving to 84% of participants at 12 months post-treatment.

Corticosteroids

- Average VAS pain score improved to 2.8 at month 3, but worsened to 4.2 by 6 months post-treatment
- Only 27% of participants achieved a VAS pain score of 3 or less ("successful outcome") 6 months post-treatment



Mean overall VAS pain score at baseline (pre-treatment) and at 1,3, 6 and 12 months post-treatment with ATI or CS.
Dashed line indicates that there was a significant drop-out in the CS group at month 6, with only 4 patients remaining by month 12
*/¥ - statistically significant differences between treatment groups

Statistically significant ASES Score outcomes

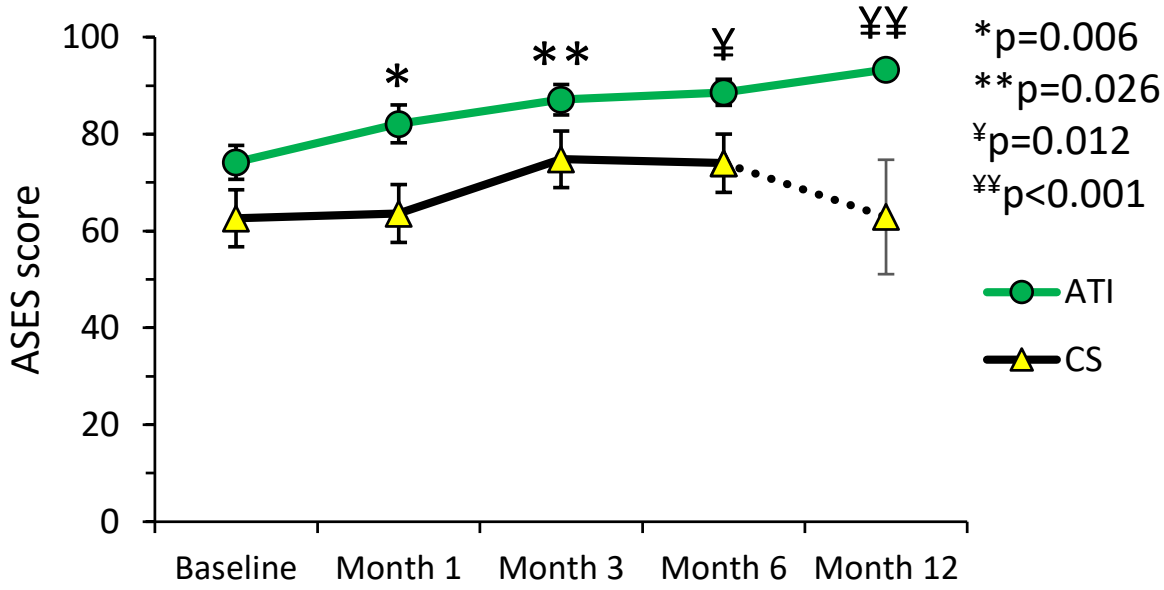
Patients randomised to OrthoATI™ experienced a significant and sustained improvement in pain and return of shoulder function after treatment.

OrthoATI™

- Average ASES score improved from 74.2 pre-treatment to 93.3 at 12 months post-treatment
- At 6 months post-treatment, 72% of participants reported an ASES score of 78.6 or better ("successful outcome"), improving to 95% of participants at 12 months post-treatment

Corticosteroids

- Average ASES score improved from 62.6 pre-treatment to 62.9 at 12 months post-treatment
- Insufficient data to accurately assess change from pre-treatment to 12 months post treatment, because 7 of 11 (64%) participants withdrew from the study prior to month 12



Mean ASES score at baseline and at 1,3, 6 and 12 months after treatment with ATI or CS.
Dashed line indicates that there was a significant drop-out in the CS group at month 6 resulting in 4 patients remaining in month 12
*/¥ - statistically significant differences between treatment groups

OrthoATI™ randomised study patient feedback

Clinical trial patient, Paul Speering commented:

"After injuring my shoulder playing community cricket, and trying many conservative treatments, I was still having trouble with everyday living tasks such as washing my hair, hanging out the washing and dressing myself. I wasn't able to play cricket or train and compete as a powerlifter. I struggled to sleep and it was quite a depressing time for me.

"I was referred to a surgeon after these conservative treatments failed, and he suggested that I check out this clinical trial that was being run. After looking at it, I decided that it may be a better option than surgery. As part of the trial, I was randomly selected to receive the cortisone injection, rather than the experimental treatment. This didn't work, and I was back to square one.

"After a few more months of pain, discomfit and disability, I then opted to receive the OrthoATI (tm) and haven't looked back. Within just a few months, I was back training in the gym, lifting weights and playing cricket. Without this treatment, I would not have been able to do the things I love again.

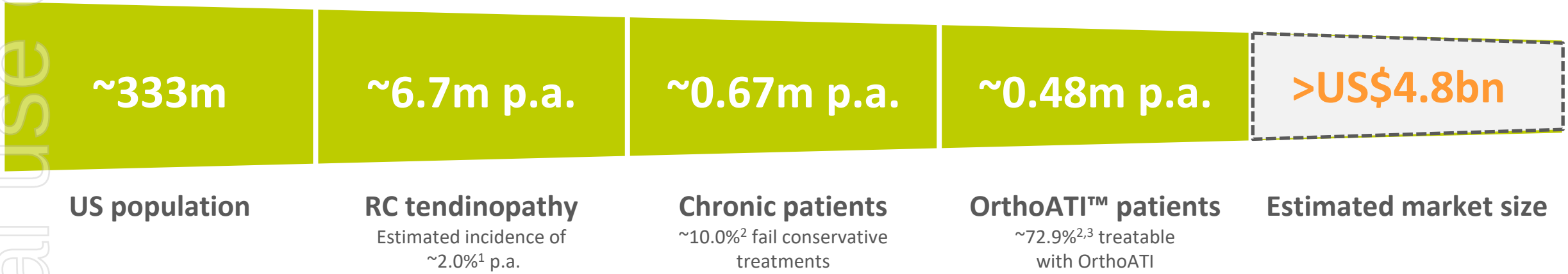
"Since the treatment, as a drug free and fully drug tested athlete, I have become both a Masters National Powerlifting Champion and the Oceanias Masters Powerlifting Champion, and hold all four State Records in my age and weight category.

"I was so fortunate to be involved in this study, and I wish that more people would be able to take advantage of the treatment. It truly has been life changing for me."

OrthoATI™ – US Rotator Cuff addressable market

OrthoATI™ is at the forefront of a large and growing market opportunity where the addressable market is estimated to be >US$4.8bn p.a.

Illustrative analysis: US Rotator Cuff addressable market



1. Littlewood et al, 2013. Shoulder and Elbow 5, pp 256 265
2. Kane et al, 2019. Am Fam Physician 100(3):pp 147-157
3. Parikh et al, 2021. Current Medical Research and Opinion, 37(7):pp 1199-1211

Significant upside value potential

Significant value upside potential exists given OrthoATI™'s large addressable market, well positioned to become first FDA-approved injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries

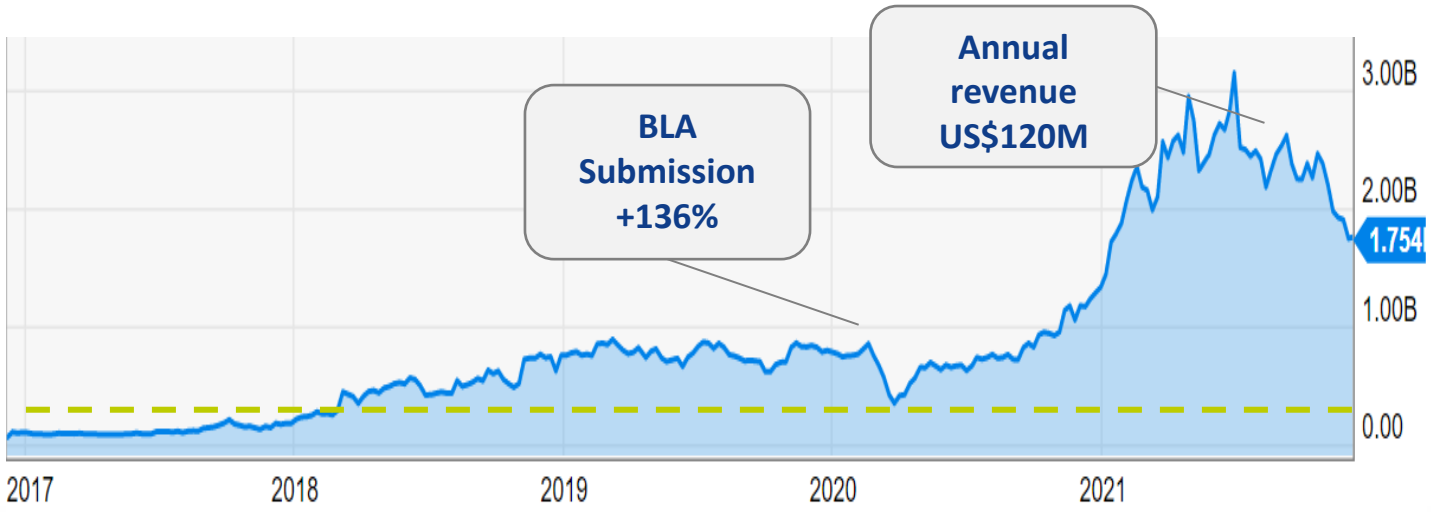
Comparison to Vericel

Develops, manufactures, and markets two regenerative medicine products for epidermal autografts and cartilage regeneration

Orthocell upside value potential

- ✓ Larger patient population
- ✓ Non-surgical intervention
- ✓ OCC founders successfully developed *MACI* (cartilage cell repair technology) – now a US$2B company (Vericel®) generating ~US$120M p.a

VERICEL **Market capitalisation (US$m)**



Vericel. www.vericel.com/investorrelations. 2021.

Orthocell's market capitalisation

OrthoATI™ – next steps

Clinical program can now be initiated in the US with manufacturing scale up and commercial support

- Technology transfer to US manufacturing and scale up of process with automation and optimisation to accommodate 1,000's of patients per month
- Advancing next interaction with FDA to approve clinical development plan and secure Regenerative Medicine Advanced Therapy (RMAT) Designation to accelerate regulatory processes, to lead to a successful Biologic License Application (BLA)
- Planning randomised clinical study under FDA supervision
- Commercial preparations, key opinion leader engagement, reimbursement and market entry activities being advanced with new team members

ortho·cell

New US based team members

Unrivaled experience with FDA regulated cell therapy product development and commercialisation

Leslie Wise

Globally recognized leader in Healthcare Economics, Market Access, Health Policy

angiodynamics

ZIMMER BIOMET

Bristol Myers Squibb™

10+ yrs Cell Therapies
10+ yrs Orthopedics

Matt Kemp

Innovator and Cell Therapy Clinical / Commercial Executive

Dendreon

ZIMMER BIOMET

Allergan

15+ yrs Cell Therapies
5 yrs Orthopedics

Brandon Miller

Senior Global Commercial Executive in Orthopedics

REBELLION SOLUTIONS

ZIMMER BIOMET

20 yrs Cell Therapies
25+ yrs Orthopedics

Dr Lara Silverman, PhD

Expert in Cell Therapy Development and Translation

DiscGenics™

10+ yrs Cell Therapies
15+ yrs Orthopedics

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