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Final data readout for Orthocell's nerve reconstruction study

- **Final data read out** of all patients in Orthocell's nerve reconstruction trial **demonstrates early recovery of muscle function to paralysed upper limbs and continued improvement between 12 and 24 months**
- **At 12 months, 76% of all reconstructed nerves (25 of 33)** resulted in functional recovery of muscles controlled by the repaired nerve, improving to **85% (23 of 27) at 24 months post treatment**
- **In the quadriplegic patient cohort, 76% (13 of 17) of reconstructed nerves** also resulted in functional recovery (MRC ≥3) of muscles controlled by the repaired nerve at **12 months**, improving to **92% (11 of 12) at 24 months post-treatment**
- Orthocell received **Australian regulatory approval for Remplir™** (formerly CelGro®) for use in peripheral nerve reconstruction procedures in March 2022
- Orthocell is in **advanced discussions with potential marketing and distribution** partners in Australia and progressing its regulatory strategy to achieve US market approval

Perth, Australia; 07 June 2022: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce completion of its Remplir™ (previously CelGro®) nerve reconstruction study. Final data read out at 24 months post-treatment for all patients in the trial shows nerve reconstruction with Remplir™ following injury to the spinal cord, brachial plexus and other peripheral arm/hand nerves consistently restores arm and hand function. The results also demonstrate that not only were functional gains maintained between 12- and 24-months post-treatment, but that patients continued to improve over that time.

Orthocell Managing Director, Paul Anderson, said: *"Consistently returning function to paralysed upper limbs was the primary goal in this study. I am delighted by the results showing early recovery and continued improvement in arm and hand function in these difficult to treat patients. This study has demonstrated higher quality outcomes, improved predictability, and consistency of return of muscle function following Remplir™ nerve reconstruction treatment."*

Patients in the clinical trial suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents, resulting in partial or total loss of use of their arms and, in more severe cases, their legs and torso as well (quadriplegia). Patients experienced significant pain and were unable to perform basic activities of daily living (i.e. eating, bathing, dressing and toileting), play sport and/or work. Without surgery they would not have regained normal use of their injured arm and hand.

Patients received one or more nerve reconstructions augmented with Remplir™ in one or both upper limbs. Recovery after treatment was assessed by grading the strength of target muscles[1] closest to the site of nerve repair. Follow up data at 12 months was available for 16 of 19 patients involving 33 nerve repairs. Results showed 76% (25 of 33) of nerve reconstructions resulted in functional recovery of muscles controlled by the reconstructed nerve. Follow-up data at 24 months post treatment was available for 14 of 19 patients involving 27 nerve reconstructions. Results showed that 85% (23 of 27) of nerve reconstructions resulted in functional recovery of target muscles closest to the reconstruction site.

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne, said: *"Remplir™ is increasing the success rate and efficiency of nerve transfer surgery. The quadriplegic results are particularly*

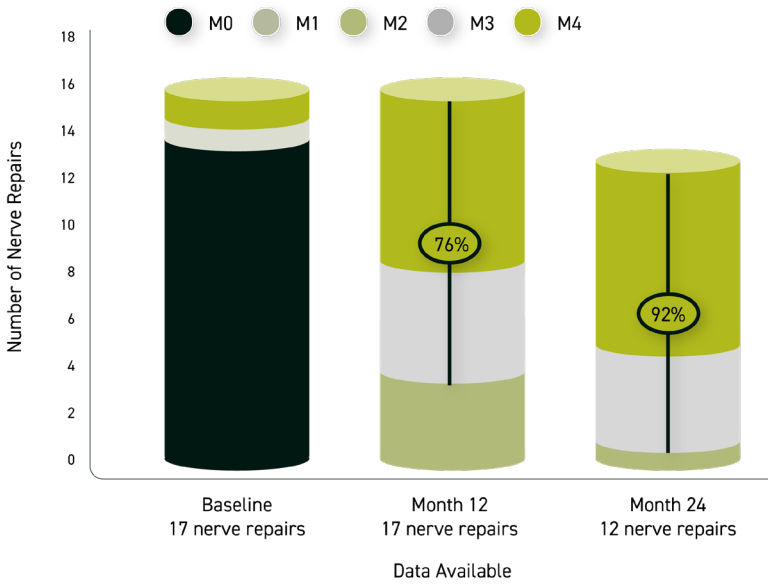
[1] *British Medical Research Council Grading System (MRC grade), with a score of 0 to 5. A score of zero (0) indicates no nerve connection to the muscle (ie., no recovery), a score of five (5) is given to muscles with normal power/strength. A score of 3 or better is clinically defined as a meaningful functional recovery.*

promising with functional gains not only maintained, but continuing to improve between 12- and 24-months post-treatment. Seeing patients regain enough independence so that they can be involved in family life and return to work is very rewarding."

Quadriplegic patient outcomes

Over half of the nerve repairs augmented with Remplir™ (17 of 33) were performed in five quadriplegic patients. The results for this challenging condition have been very encouraging. Patients demonstrated faster and better results in muscle function restoration compared to published studies[2] of nerve transfer surgery using the standard method (direct suture). In particular, **76% of the quadriplegic nerve transfers (13 of 17) resulted in the best-case clinical outcome for target muscles (MRC Grade 3 or 4[1])** at 12 months post treatment, improving to **92% (11 of 12) at 24 months post-treatment** (Figure 1). An MRC Grade 3 or 4 means quadriplegic patients regain a level of independence, enabling them to perform tasks such as brushing teeth, drinking from a cup, and transferring into and out of a wheelchair without assistance.

Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia



Grade 3 and 4 – voluntary movement with improved strength and range of motion. **Maximum level of recovery expected.**

Grade 2 – voluntary movement restored, limited strength and range of movement.

Grade 0 or 1 – no voluntary movement.

Trial participant Damien Hall injured his hand skateboarding, seriously damaging a motor nerve leaving him with a permanently closed fist, significantly affecting activities of daily living. Damien's recovery has been impressive.

"The treatment I received to repair my nerve damage has been completely life altering. I had lost full function of my hand, making the simplest of tasks impossible – from tying my own shoelaces to changing my baby's nappy. After being in the trial, I have made a full recovery and am now able to complete tasks unassisted and pain-free giving me back my freedom and independence. The treatment has also allowed me to return to the

[2] Orthocell meta-analysis of published studies evaluating nerve transfer in quadriplegia

sport I love of rock climbing, where I am performing at the same level prior to my injury including competition climbing," said Damien.

Figure 2: Trial Participant Damien Hall

Why are the final nerve reconstruction results significant?
The Company believes Remplir™ to be an important step forward for improving nerve reconstruction surgery. Its ease of use, consistent and predictable high-quality outcomes, which are achieved in a shorter timeframe compared to other methods, will empower surgeons to improve the lives of patients with these complex injuries.

Remplir™'s global addressable market in peripheral nerve reconstruction is estimated to be worth more than US$7.5 billion per annum, with approximately 3,000,000[3] procedures that could use Remplir™ completed each year.

Next Steps
Remplir™ received Australian regulatory approval in March 2022 and the Company is progressing discussions with potential marketing and distribution partners in Australia.

[3] *Addressable markets include US, Japanese, European and Australian markets. Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.*

With this positive data from the Remplir™ nerve reconstruction trial, Orthocell is also preparing for discussions with the FDA on the appropriate approval pathway for Remplir™ and engaging with US key opinion leaders and insurers to finalise the commercialisation approach for registration and reimbursement of Remplir™. The data has been submitted for publication.

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: paul.anderson@orthocell.com.au

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

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 bone and soft tissue injuries. Orthocell's portfolio of products include CelGro™, a collagen medical device which facilitates tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications and is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia (ARTG). SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

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.