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advancing tissue repair & regeneration

Positive CelGro® nerve regeneration results in quadriplegic patients

- **Data read out** of all patients in the CelGro® nerve regeneration trial **demonstrates potential for breakthrough nerve treatment to return function to paralysed upper limbs**
- **75.8% of all nerve repairs (25 of 33) in the clinical study resulted in functional recovery** (MRC grade 3 or 4[1]) **of muscles controlled by the repaired nerve** at 12 months post treatment
- **In the quadriplegic patient cohort, 76.5% of nerve repairs (13 of 17) also resulted in functional recovery** (MRC grade 3 or 4[1]) **of muscles controlled by the repaired nerve** at 12 months post treatment
- **Final 24-month results of all patients in the CelGro® nerve regeneration study expected in Q2 CY2022** – with key regulatory milestones progressing in US and AU

Perth, Australia; 21 June 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the first interim data read out of all patients in the CelGro® nerve regeneration trial at 12 months post treatment. Positive clinical data shows nerve repair with CelGro® following injury to the spinal cord, brachial plexus and other peripheral arm/hand nerves consistently restores arm and hand function.

Orthocell Managing Director, Paul Anderson, said: *"Consistently returning function to paralysed upper limbs is the primary goal in this study. I am delighted by the 12-month follow up results, our most complete data set to date, demonstrating higher quality outcomes, improved predictability, and consistency of return of muscle function following CelGro® nerve regeneration 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 repairs augmented with CelGro® 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 **75.8% (25 of 33) of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve.**

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne, said: *"We are now seeing a consistent return of arm and hand function following nerve transfer surgery with CelGro®. The quadriplegic patient results are particularly promising, with improved results at 12 months post treatment compared to the literature. CelGro® is increasing the success rate and efficiency of nerve transfer surgery. Seeing patients regain enough independence so that they can be involved in family life and return to work is very rewarding."*

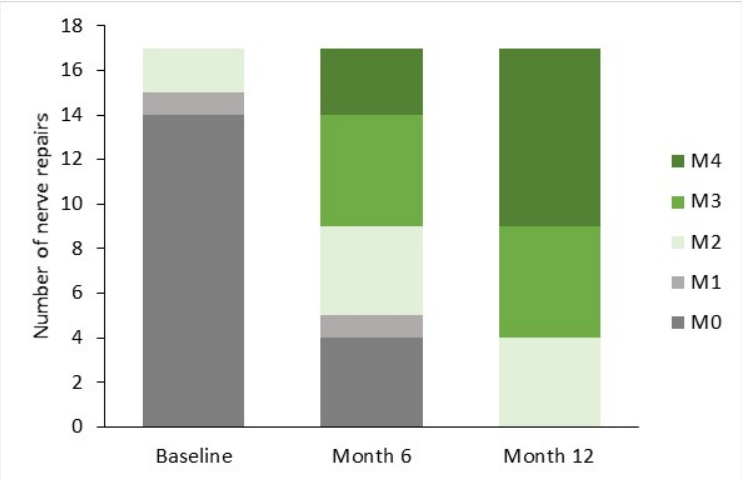
Quadriplegic patient outcomes

Over half of the nerve repairs augmented with CelGro® (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 of nerve transfer surgery using the

[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.*

standard method (direct suture). In particular, **76.5% of the quadriplegic nerve transfers (13 of 17) resulted in the best-case clinical outcome (MRC Grade 3 or 4[1])** at 12 months post treatment (see 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 Adrian Walsh (Figure 2) broke his neck in a mountain bike accident in June 2017 and didn't have enough strength to use a wheelchair on his own. Adrian's recovery has been impressive.

"This treatment has made a world of difference to me. The increased strength and mobility in my arm and hand has really boosted my independence. I am contributing more around the home and can help my wife and kids – it feels good. My new modified car is great too, I have already done 10,000km's, driving the family around, going to rugby training and doing the school runs." **Hear Adrian and his surgeon, Dr Alex O'Beirne, talk about their experiences, the nerve transfer procedure and his recovery at 12 months post treatment, here.**

Figure 2: Adrian Walsh (far left) wheelchair rugby national champion – following treatment with CelGro®

Why are the interim nerve regeneration results significant?
The Company believes CelGro® to be an important step forward for improving nerve repair 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.

CelGro®'s global addressable market in peripheral nerve repair is estimated to be worth more than US$7.5 billion per annum, with approximately 3,000,000[2] procedures that could use CelGro® completed each year.

Next Steps
With positive 12-month data in hand from the CelGro® nerve regeneration trial, Orthocell is now preparing for discussions with FDA on the approval pathway and also with US insurance companies (or 'payers') and key opinion leaders to finalise the commercialisation approach for registration and reimbursement.

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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 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

[2] 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.

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.