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Positive CelGro® nerve regeneration results in quadriplegic patients

- **96% of nerve repairs restored voluntary movement** to previously paralysed muscles
- **All quadriplegic patients increased movement and power of affected muscles** following CelGro® nerve regeneration treatment
- **86% of patients who required prescription medication** (including opioid-based medications) for chronic nerve pain were able to **significantly reduce or cease their use**
- Nerve repair with **CelGro® resulted in predictable and consistent restoration of muscle function**
- **Patient treatment 75% complete.** Recruitment expected to be completed by Q4 CY 2019.

Perth, Australia; 09th October 2019: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce positive interim clinical results for the use of CelGro® for enhancing repair of peripheral nerves. Following surgery with CelGro®, patients have regained muscle function in the affected limbs and have either ceased or significantly reduced prescription pain medication (including opioid-based medications).

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne, said: *"Observing the positive progress of the initial patients gave me the confidence to use CelGro® in more severe cases, such as quadriplegia. The microsurgery required to return arm or hand function to quadriplegic patients is complex and challenging, and can require multiple nerve repairs. CelGro® facilitates tensionless repair, and can prevent regenerating nerves being compressed or trapped by scar tissue. I am very pleased with these patients' progress, and their arm and hand function continues to improve."*

Patients participating in the clinical trial had previously suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents, resulting in impaired use of the affected limbs and, in more severe cases, quadriplegia (partial or total loss of use of all four limbs and torso). Some patients experienced significant pain and were unable to perform basic daily tasks (eg. eating, bathing, and dressing) without assistance. In many cases, patients were unable to work and participate in recreational activities.

A clinical follow-up of the first twelve participants 12 months after surgery found voluntary muscle movement was restored in 96% of nerve repairs, and 86% of patients who required prescription pain medication, including opioid-based medications, were able to significantly reduce or stop their medication completely.

Trial participant Adrian Walsh, said *"When the accident happened, I knew straight away that I couldn't feel my legs. All I could think about at that moment, laying still on my back, was my wife and three kids. Although I regained some movement in my arms over time, I still couldn't use my wheelchair properly. When I heard about the CelGro® trial, I thought it was worth a try. My arm now feels 500* percent *better than before the procedure. Since being in the trial I've managed our house renovation, I go to the gym a couple of times a week, and play wheelchair rugby. I've just started studying a double diploma in Project Management and Building Construction Management too, because I really want to work again. It's been so worth it."*

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Case report: Adrian Walsh

Adrian Walsh (43) was diagnosed with quadriplegia after he broke his neck in a mountain bike accident in June 2017. He retained some movement in his elbows and upper arms, but his hands, torso, and legs were paralysed and his arms didn't have enough strength to use a wheelchair on his own. Since his treatment with CelGro®, Adrian's improved arm strength and function has given him more independence and the ability to take on new challenges.

This short film demonstrates Adrian's improved mobility following treatment with CelGro®: Watch it at https://www.orthocell.com.au/patientvideo

Clinical Study Interim Results

Orthocell's clinical trial aims to demonstrate the effectiveness of CelGro® in improving patient outcomes after nerve repair. The trial is being undertaken with leading Australian orthopaedic nerve specialist Dr Alex O'Beirne, of St John of God Hospital Murdoch, Jaslyn Cullen Occupational Therapy Services and Professor Ming Hao Zheng, of the University of Western Australia.

The study will investigate a total of 20 patients who had an injury that severed the connection between the peripheral nerves in the arm, brachial plexus or spinal cord, causing loss of function or paralysis in the arm and/or hand. CelGro® will be used together with microsurgery to repair the damaged nerves and re-establish the connections to target muscles.

Patients currently enrolled in the clinical study received one or several nerve repairs augmented with CelGro® in one or both upper limbs. Functional recovery after treatment was assessed by grading the power[1] of target muscles closest to the site of nerve repair. Assessments were performed before treatment and will be repeated for up to 24 months after treatment.

An interim review of the first twelve study participants, 12 months after treatment, involving twenty-five nerve transfers augmented with CelGro®, has been completed. Participants had nerve injuries of varying severity, from peripheral nerve injury (3 patients), to more complex injuries of the brachial plexus and spinal cord (9 patients in total), resulting in impaired use of the affected limbs and in the more severe cases, quadriplegia.

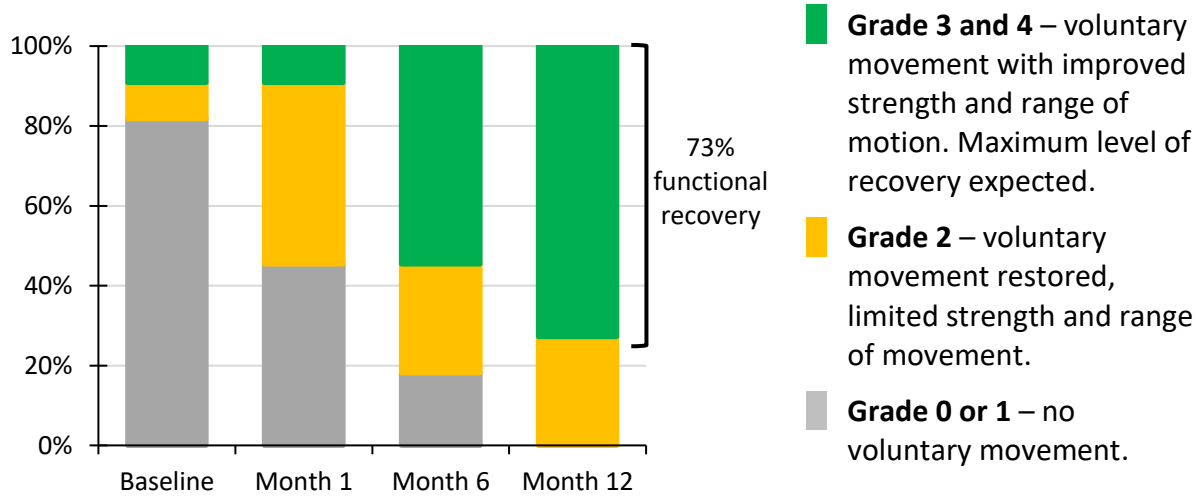
[1] *British Medical Research Council Grading System (MRC grade), with a score of 0 to 5. A score of zero (0) indicates no nerve connection to the muscle (ie., no recovery), a score of five (5) is given to muscles with normal power/strength. Patients with this type of injury rarely recover full power.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

Results at 12 months after treatment with CelGro®:

- **96% of nerve repairs restored voluntary movement** to previously paralysed muscles (MRC Grade 2 or better[2])
- **66% of nerve repairs resulted in meaningful functional recovery of muscles** controlled by the repaired nerve (MRC grade 3 or 4)
- **86% of patients** who required prescription medication (including opioid-based medications) for chronic nerve pain were able to **significantly reduce or cease their use**

Almost half the nerve repairs (11 of 25) were performed in **three quadriplegic patients**. The results in these challenging patients have been encouraging, with **73% of nerve repairs resulting in meaningful functional recovery (MRC grade 3 or 4) of affected muscles within 12 months** (see Figure 1). A quadriplegic patient with complete paralysis regained sufficient arm and hand function to perform tasks such as brushing teeth, drinking from a cup, and transferring into and out of his wheelchair.

Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia (11 nerve repairs)



Why are the interim nerve regeneration results significant?

Nerve repair using CelGro® resulted in improvements in muscle power at 12 months that were comparable to what would normally be expected at 24 months with other methods. The consistent and predictable outcomes of nerve repair with CelGro®, achieved in a shorter time, will empower surgeons to improve the lives of patients with these complex injuries.

CelGro® facilitates tensionless repair of peripheral nerves and is of significant clinical interest to the surgical community (eg. Orthopaedics and neurosurgery) because of the potential improvements in efficacy and efficiency of surgical procedures. Tensionless repair will reduce surgery time and the risk of additional trauma to soft tissue through the use of sutures.

[2] *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. Patients with this type of injury rarely recover full power. A score of 3 or better is clinically defined as a meaningful functional recovery.*

Orthocell has a clear commercialisation strategy for the CelGro® nerve regeneration indication and intends to leverage these results and the recent European approval of CelGro® for regulatory submission in the US, EU and Australia.

Orthocell Managing Director Paul Anderson, said: *"The results reinforce the initial patient outcomes previously reported from our clinical study demonstrating improved predictability and consistency of return of muscle function following CelGro® nerve regeneration treatment."*

"Seeing one of our patients progress from no strength in his arm, and no movement in his fingers and thumb, to playing wheelchair rugby is extremely encouraging for our researchers and clinical partners. We feel we are making a significant breakthrough for the repair of damaged nerves – CelGro® is greatly improving quality of life for people with limited treatment options."

"Off the back of these positive interim results, our team is accelerating regulatory applications in the US, EU and Australia to make this treatment accessible to the more than 700,000 people who experience nerve damage annually."

CelGro® addressable market in peripheral nerve repair

In the US alone, over 20 million people suffer from peripheral nerve injury as a result of motor vehicle, sporting or work-related incidents, at an annual cost of approximately US$150 billion. Many of these injuries require surgical nerve reconstruction involving the use of artificial "conduits" or synthetic sheaths that are secured in place with sutures.

To address the disadvantages of suturing, Orthocell designed CelGro® with handling characteristics to assist surgeons with performing complex reconstructive surgical procedures and to enable the tensionless repair of soft tissue defects.

CelGro®'s addressable market in peripheral nerve repair is estimated to be worth more than US$1.1 billion per annum, with approximately 700,000 procedures that could use CelGro® completed each year. Market growth is expected to be underpinned by the surgeons' preference for quality and functional bio-absorbable membranes.

The company believes CelGro® represents a breakthrough in soft tissue reconstruction and offers significant global commercial potential in its existing addressable markets of bone, tendon, nerve and cartilage as well as much wider applications in general surgical and soft tissue reconstructive applications.

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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 orthopaedic, reconstructive and surgical applications. Orthocell recently received European regulatory approval (CE Mark) for CelGro®. The collagen medical device can now be marketed and sold within the European Union for a range of dental bone and soft tissue regeneration procedures and is being readied for first approval in the US and AUS. The Company's other major products are the TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. 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 www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd