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First Patients Complete Nerve Regeneration Trial

- **Patients regain sensation and muscle function in affected limbs** following CelGro® nerve regeneration treatment
- **Patients experience 83% improvement in muscle power**
- Results indicate **CelGro® can be used to guide and support nerve regeneration** in severely damaged or severed peripheral nerves of the hand and upper limb
- **Patient treatment 75% complete.** Recruitment expected to be completed by Q2 CY2019

Perth, Australia; 08th May 2019: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce that the first four patients have successfully completed participation in the CelGro® nerve regeneration clinical trial. Following surgery with CelGro®, patients have regained muscle function and/or sensation of affected limbs and have returned to work, sport and activities of daily living. The trial is being undertaken with leading West Australian orthopaedic nerve specialist, Dr Alex O'Beirne of St John of God Subiaco Hospital and Professor Ming Hao Zheng of the University of Western Australia.

Dr Alex O'Beirne, said: "The nerve injuries suffered by the patients in this study were so severe that they would not have been able to regain normal use of their injured arm and hand without microsurgery. The surgery can be very complex and difficult, but using CelGro® has enabled us to rejoin severed nerves without tension. CelGro® increases the strength and quality of the repair and makes surgery easier. I am very pleased with the patients' progress, regaining use of affected limbs faster than I would have expected and they continue to improve."

The first four patients treated in this pivotal trial had previously suffered traumatic peripheral nerve injuries following motor vehicle, sporting and work-related incidents, resulting in complete paralysis, or impaired use of the upper limb. Patients experienced significant pain and were unable to perform basic activities of daily living (i.e eating, bathing, dressing and toileting), playing sport and/or working.

A review of clinical results 24 months after nerve regeneration treatment with CelGro® (involving the repair of 8 peripheral nerves) indicates that CelGro® successfully guides and supports nerve regeneration in severely damaged peripheral nerves of the hand and upper limb. Patients regained muscle function and/or sensation of affected limbs and have commenced return to work, sport and activities of daily living following CelGro® nerve regeneration treatment. A short video explaining how CelGro™ supports nerve repair can be found here. https://www.orthocell.com.au/celgro-nerve-1

Patient Daniel Hunt, said: After my football injury, I had no feeling in my right shoulder. I couldn't pick up my kids, swim, or play football. When Dr O'Beirne said that being in the CelGro® study might improve outcomes, I thought it would be worth trying. I'm living a normal life now. I can pick up my kids and I even swam a duo to Rottnest! I might even be able to play footy again next year - something that I thought would never happen.

Additional information about the CelGro® Nerve Regeneration Trial

Orthocell conducted the trial to demonstrate that the company's collagen medical device CelGro® can be used to guide and promote tensionless nerve regeneration in damaged peripheral nerves of the hand and upper limb. The study involves 20 patients with traumatic nerve injury requiring surgical repair. Orthocell has treated 75% of patients (15 of 20), with recruitment expected to be completed by Q2 CY2019.

Muscle function/power following CelGro® nerve regeneration treatment was measured using the British Medical Research Council Grading System, with a score of 0 to 5. A score of zero (0) indicates inability to contract the affected muscle, a score of five (5) indicates an optimal result, where the newly regenerated nerve has restored normal/full power of affected muscles. Sensory function was also assessed using the static and moving two-point discrimination test.

Prior to surgery with CelGro®, the first four patients scored a muscle power of zero (0), with complete paralysis or significant difficulties in performing activities of daily living. Following CelGro® nerve regeneration treatment, the first four patients all scored a muscle power of four (4), representing an 83% improvement.

The very positive results indicate CelGro® can accelerate and augment the repair of damaged or severed nerves. Tensionless repair of peripheral nerves is of significant clinical interest to the orthopaedic community because of the potential improvements in efficiency and efficacy of surgical procedures. Tensionless repair will reduce surgery time and the risk of additional trauma to soft tissue through the use of sutures. This study also further validates the versatility of CelGro® and the potential to extend Orthocell's orthopaedic product range.

Orthocell Managing Director, Paul Anderson, said: "The first patient outcomes are very positive with early results indicating CelGro® is effective in guiding and regenerating peripheral nerves. This is an important step forward in the development of the CelGro® platform in the area of human nerve regeneration. CelGro® allows for tensionless reconnection of the damaged nerve while guiding nerve regeneration and accelerating the healing process."

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

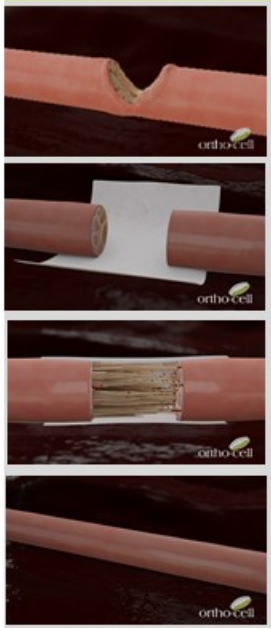
CelGro®'s addressable market in peripheral nerve repair is estimated to be worth more than US$1.1 billion per annum, with approximately 700,000 procedures that could use CelGro® completed each year. Market growth is expected to be underpinned by the surgeons' preference for quality and functional bio-absorbable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

Example of tensionless repair of soft tissue

e.g. Peripheral nerve repair procedure



1. Peripheral Nerve Injury
Crushed peripheral nerve after traumatic injury to limb

2. Preparation of Repair Site
CelGro® is secured around nerve ends, forming a sealed conduit

3. CelGro® guides and supports nerve repair
New nerve fibres reconnect

4. Nerve Healing
Healed nerve restores function and sensation to affected limb

About the CelGro® Platform

CelGro® is a collagen medical device platform for soft tissue regeneration and repair applications, manufactured by Orthocell at its quality-controlled Good Manufacturing Practices (GMP)-licensed facility in WA.

Orthocell has received market authorisation (CE Mark) of CelGro® in the EU for dental bone and soft tissue applications. The CE Mark allows CelGro® to be sold within EU countries, validates CelGro®'s quality manufacturing and product performance, and provides a strong foundation for indication expansion and regulatory approvals.

CelGro® has also been shown to improve tissue growth and repair in clinical studies using CelGro® to augment repair of the rotator cuff tendon within the shoulder, to guide bone regeneration in the jaw and to assist in the rejoining of severed, or damaged peripheral nerves. CelGro® is a customisable collagen medical device with numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue repair.

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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 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. The Company's other major product is the CelGro® platform technology, 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.

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