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# US Nerve Repair Study Design Meets FDA Requirements

- FDA confirms CelGro® Nerve regeneration study design meets US 510(k) submission requirements
- US 510(k) study expected to commence Q1 CY2020
- Follows recent study results showing CelGro® facilitates high quality nerve repair and restores function to previously paralysed muscles
- Orthocell is well positioned to accelerate US, EU and AUS regulatory approvals and commercialisation of CelGro®
- CelGro®'s addressable market in peripheral nerve repair is estimated to be worth more than US$1.1 billion per annum

**Perth, Australia; 16 December 2019**: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce that it has received confirmation from the FDA that the proposed CelGro® nerve regeneration animal study protocol meets requirements to support the near term 510(k) submission. The Company has now accelerated ethics applications to commence the study in Q1 CY2020.

***Orthocell Managing Director Paul Anderson said:*** "With the safety and efficacy of the CelGro® nerve repair product established, Orthocell is accelerating its regulatory program to gain approval in the US, EU and AUS. We are very pleased with the FDA feedback and are well positioned to gain approval of CelGro® in the US, the largest health care market. "

Following recent successful CelGro® nerve repair study results and growing demand from industry leading clinicians and potential partners for superior nerve repair medical devices, the Company commenced pre-submission activities with the FDA to confirm the requirements for US market approval. Recent feedback from the FDA confirmed the proposed CelGro® nerve regeneration animal study protocol was suitable to support an evaluation of substantial equivalence to an approved nerve repair device, meeting the requirements of the US 510(k) predicate product regulatory pathway.

The study is titled "Evaluation of collagen nerve wraps used in peripheral nerve repair in a rat sciatic nerve injury model" and is designed to provide evidence of safety and performance of CelGro® in peripheral nerve repair using the well-established animal model. The study will involve the treatment of severed sciatic nerves in approximately seventy two (72) rats in three (3) study groups (control, CelGro® and comparator) with outcome measures recorded at four, eight and twenty weeks post treatment. The key outcome measures include the performance of CelGro® in facilitating high quality nerve regeneration and restoration of motor and sensory function. The Company aims to complete the study and submit the 510(k) application in Q3 CY2020.

**Significance of recent CelGro® nerve repair study results**

Recent results indicated nerve repair using CelGro® resulted in improvements in muscle power at 12 months that were comparable to repair typically achieved 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.

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

**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 sutured to the nerve.

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 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.

Orthocell has a clear commercialisation strategy for the CelGro® nerve regeneration indication and intends to accelerate US, EU and AUS regulatory submissions.

**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: paulanderson@orthocell.com.au

## Media enquiries

**Haley Chartres**
**Hales² Consultancy**

P: +61 423 139 163
E: haley@h-squared.com.au

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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

**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.