Orthocell secures patents for suture-less repair of soft tissue

- **Patents granted in Canada and Hong Kong for CelGro® for suture-less repair of soft tissue defects – in addition to previously granted patents in Australia, New Zealand, China and Japan**
- **Patents cover the method of using CelGro® to repair a defect in soft tissue, such as tendons, ligaments and nerves, avoiding the use of damaging sutures**
- **Pre-clinical and clinical results show suture-less repair of soft tissue has potential to greatly improve the efficiency and efficacy of surgical procedures**
- **Orthocell is progressing CelGro® nerve regeneration US FDA submission to confirm the most appropriate US regulatory pathway and potential for inclusion in expedited programs**

Perth, Australia; 07 September2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce new patents have been granted in Canada and Hong Kong for its novel CelGro® collagen medical device platform for soft tissue regeneration applications.

The patents titled **"Suture-less repair of soft tissue"** are now approved in Australia, New Zealand, China, Japan, Hong Kong, and Canada, with further applications progressing in US and EU. The patents are set to expire on 12 October 2035.

Orthocell Managing Director, Paul Anderson, said: *"These patents are an important addition to our global intellectual property portfolio, further strengthening our position in regenerative medicine product development and novel surgical techniques for soft tissue repair. Suture-less or tensionless repair is of particular importance in the optimal repair of damaged nerves and is a key part of the repair process undertaken in the CelGro® nerve regeneration clinical study. This comes at a perfect time for the Company as we move our exciting pipeline products in nerve, tendon and ligament repair through the registration process in the US, EU and AUS."*

Suture-less repair of soft tissue refers to the method of repairing damaged soft tissue without the use of damaging sutures/stitches. Suture-less repair has the potential to greatly improve the efficiency and efficacy of surgical procedures by simplifying techniques, reducing surgery time and reducing the risk of additional trauma to soft tissue caused by the use or stitches.

CelGro® versus direct suture method

Repair of damaged peripheral nerves often involves reconstructive surgery and the use of stitches to reconnect the nerve ends. Orthocell's pre-clinical studies have shown at a microscopic level that CelGro® produces superior nerve repair and return of muscle function in severed peripheral nerves when compared to the traditional (direct suture) repair method. CelGro® facilitated a tensionless repair whilst maintaining alignment of nerve ends during surgical reconnection, resulting in a repair indistinguishable from normal nerve structure. CelGro® also facilitated a 30% greater transmission of electrical impulses and corresponding muscle function. By comparison, the direct suture method caused scarring and fibrosis impeding nerve growth,

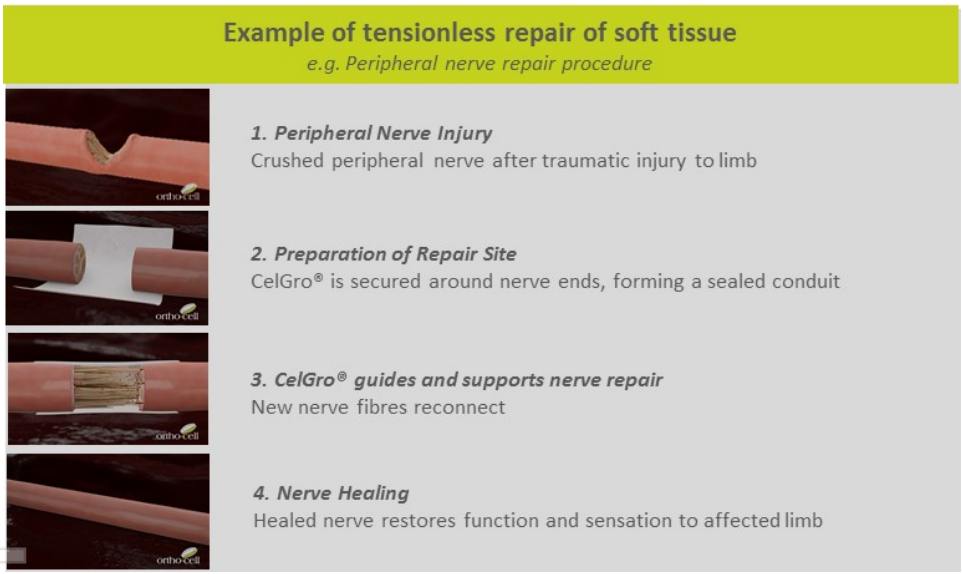
leading to disordered nerve alignment and inferior repair. Further details from this pre-clinical study were published to the ASX in July 2019, see here: "CelGro® pre-clinical study validates high quality nerve repair".

CelGro® human nerve regeneration study

Orthocell has now completed patient treatments in its CelGro® nerve regeneration clinical study involving 19 patients and 33 nerve repairs. 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. In summary:

- **75.8% of all nerve repairs (25 of 33) in the clinical study resulted in functional recovery** (MRC grade 3 or 41) of muscles controlled by the repaired nerve at 12 months post treatment; and
- **In the quadriplegic patient cohort, 76.5% of nerve repairs (13 of 17) also resulted in functional recovery** (MRC grade 3 or 41) of muscles controlled by the repaired nerve at 12 months post treatment

Further details from this study were published to the ASX in June 2021, see here: "Positive CelGro® nerve regeneration results".



Example: Suture-less or tensionless repair of soft tissue

Regulatory pathway

These results show superior nerve regeneration when compared to the market leading nerve repair device, positioning **CelGro® as the potential market leader in nerve regeneration and restoration of voluntary muscle control of paralysed upper limbs.**

The Company has now engaged Experien Group as its US regulatory advisory team to evaluate opportunities for expedited approval of CelGro® for nerve regeneration. The evaluation has been completed and Experien is **now developing the US FDA submission to confirm the most appropriate US regulatory pathway**, which includes potential for inclusion in expedited programs and clarity regarding the reimbursement value of the product.

About CelGro®

Orthocell has secured 11 patent families covering its portfolio of breakthrough regenerative medicine products, comprising 110 separate patents/applications, of which 80 are granted. CelGro® is a customisable collagen medical device manufactured by the Company at its quality controlled (GMP) facility in WA, using the Company's proprietary SMRT™ tissue engineering process. The Company has validated that CelGro® has numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell biocompatibility, tensile strength and the promotion of high-quality tissue repair. Use of CelGro® has shown to result in high quality outcomes in the repair of bone defects in the jaw, assist in the re-joining of severed or damaged peripheral nerves and augment repair of the rotator cuff tendon within the shoulder.

Release authorised by Orthocell Ltd Managing Director, Paul Anderson.

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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 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