Orthocell secures patents for sutureless repair of soft tissue

- **Patents granted in China and New Zealand for CelGro® for sutureless repair of soft tissue defects – in addition to previously granted patents in Australia 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 sutureless repair of soft tissue has potential to greatly improve the efficiency and efficacy of surgical procedures**
- **CelGro® nerve clinical trial data from all patients at 12 months post treatment is on track for release in Q2 CY2021**

Perth, Australia; 16 June 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce Chinese and New Zealand patents have been granted for its novel CelGro® collagen medical device platform for soft tissue regeneration applications. The patents titled **"Sutureless repair of soft tissue"** are now approved in Australia, New Zealand, China and Japan, 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. Sutureless 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."

Sutureless repair of soft tissue refers to the method of repairing damaged soft tissue without the use of damaging sutures/stiches. Sutureless 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.

Orthocell's patented method of sutureless repair (example below) involves the use of CelGro®, a resorbable collagen medical device that, when implanted at the site of tissue injury, acts as a cell scaffold, forming a favourable micro-environment that encourages new cell growth **(Figure 1).** Cells (red) from the regenerating tissue integrate with the collagen fibres (green) to guide tissue regeneration.

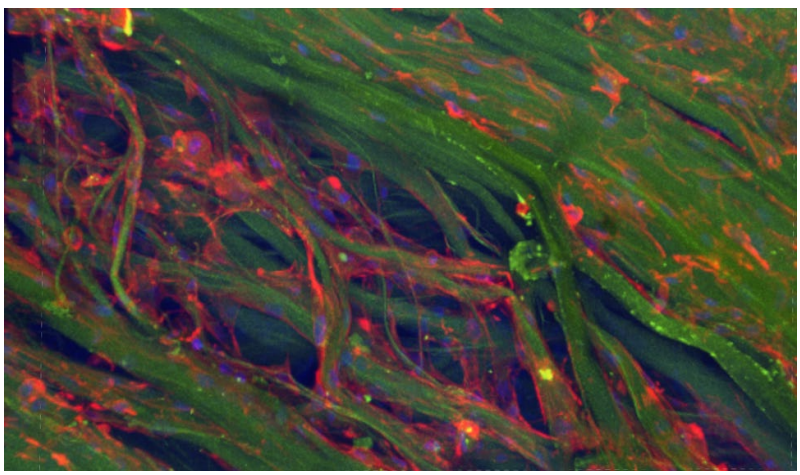

Figure 1: Fluorescence image of cells on CelGro®

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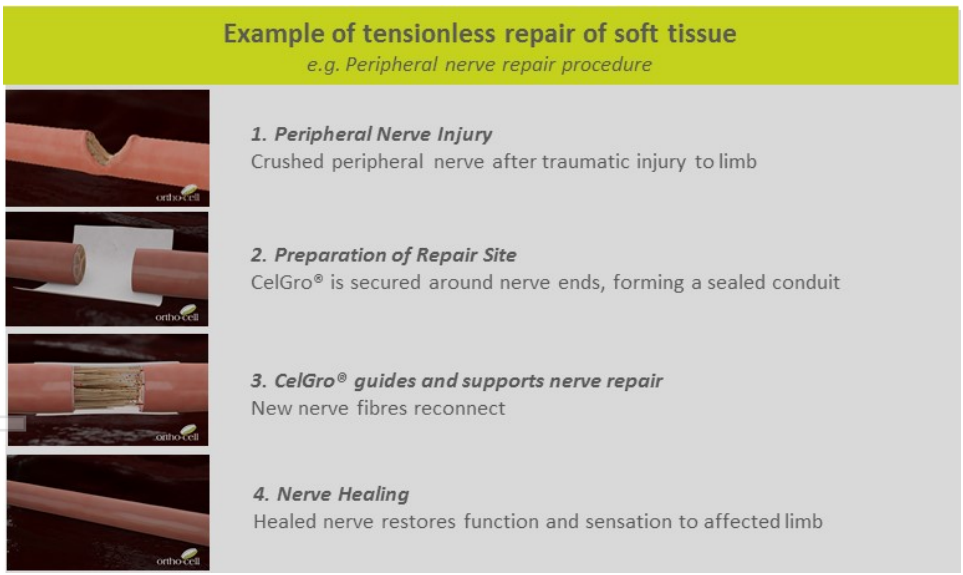
CelGro® versus direct suture method

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. Refer to ASX release "CelGro® pre-clinical study validates high quality nerve repair" for further details.

CelGro® human nerve regeneration study

Orthocell has completed patient treatments in its CelGro® nerve regeneration clinical study involving 19 patients and 36 nerve repairs. 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). Progress results to date have shown restoration of arm and hand function. **The Company is in the process of completing analysis of clinical trial data from all patients at 12 months post treatment and is on track to provide a full report of study results in 2Q CY2021.**



Example: Sutureless or tensionless repair of soft tissue

About CelGro®

Orthocell has secured 11 patent families covering its portfolio of breakthrough regenerative medicine products, comprising 110 separate patents/applications, of which 77 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 SMRTTM tissue engineering process. The Company believes 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 Paul Anderson, Managing Director, Orthocell Ltd.

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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 **@Orthocelltd** 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