New collagen rope patent for CelGro® platform technology

- **China and Hong Kong patent granted** for CelGro® collagen rope
- **Patent covers** novel collagen ropes to augment ligament repair surgeries, such as **Anterior Cruciate Ligament (ACL) reconstruction**
- CelGro® collagen rope patents **now granted in the US, Australia, China and Hong Kong**
- **Multi-billion market opportunity** for the first "off the shelf" biological solution for ACL reconstruction[1]
- **Final pre-clinical results for Orthocell's ACL reconstruction study are expected in Q3 CY2021**

Perth, Australia; 26 May 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce Chinese and Hong Kong patents have been granted for its novel CelGro® collagen rope device, to augment the surgical repair of Anterior Cruciate Ligament (ACL) injuries.

The patents entitled "**Collagen Construct and Method for Producing the Collagen Construct**" are now approved in United States, Australia, Japan, China and Hong Kong, providing additional important intellectual property protection for the CelGro® platform for soft tissue regeneration and repair applications. They are set to expire on or after 12 October 2035.

Orthocell Managing Director Paul Anderson said: *"There are currently no biological off-the-shelf solutions that mimic human ligament to enable the optimal repair of ACL injuries. The CelGro® collagen rope addresses this problem. It is designed to augment ACL reconstruction without the need to harvest the patient's hamstring or patella tendon and will disrupt the sports injury repair market by dramatically improving ACL surgery outcomes. We are extremely excited by the potential of this novel technology and I look forward to releasing the pre-clinical results in Q3 CY2021."*

Anterior cruciate ligament injuries

The ACL is one of the major stabilising ligaments of the knee. It connects the thigh bone (femur) to the shin bone (tibia), and once it ruptures, it is incapable of healing.

The ACL can be injured in several ways, such as changing direction rapidly, landing from a jump and direct contact or impact (Figure 1).

Figure 1: ACL injury

[1] Societal and Economic Impact of Anterior Cruciate Ligament Tears (2013) 1715-1759 Journal of Bone and Joint Surgery Oct 2; 95(19) Mather, RC et al

A ruptured ACL is a common injury suffered by active people, usually requiring surgical intervention, with a long period for rehabilitation before returning to preinjury activities.

Approximately 15,000 ACL knee reconstructions are done annually in Australia and up to 200,000 per year in the United States alone, with up to a quarter of patients needing additional or revision surgery.[2] The lifetime burden of ACL tears in the US alone, is estimated to be more than $7.5 billion annually when treated with an ACL reconstruction and $17.5 billion when treated with rehabilitation.[3]

Current surgical repair methods

Reconstructing the ACL mostly involves a hamstring graft, where part of the patient's tendon is surgically removed and used to replace the ruptured ACL. However, harvesting the patients hamstring tendon has many downsides, is time consuming, and can result in donor site morbidity leaving the patient prone to hamstring tears or strains during rehabilitation. Additionally, it can extend recovery time and the repaired ACL can also rupture.

The CelGro® collagen rope solution

Orthocell has developed an alternative to harvesting the patient's tendons in the form of a CelGro® collagen rope made from braided collagen fibers (see Figure 2: CelGro® collagen rope). The Company believes its CelGro® collagen rope has the potential to significantly improve treatment efficiency and effectiveness by simplifying repair techniques, reducing surgery time and mitigating the risks associated with harvesting the patient's hamstring tendon (see Figure 3: ACL repair using CelGro® collagen rope). The CelGro® collagen rope could also assist in returning patients to elite sport sooner.

Figure 2: CelGro® collagen rope

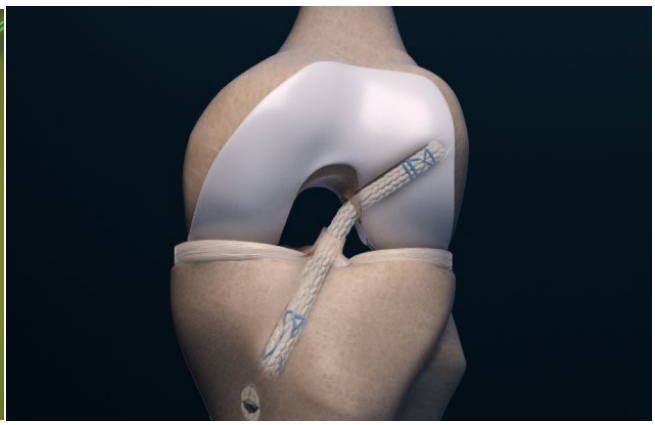

Figure 3: ACL repair using CelGro® collagen rope

[2] American Academy of Orthopaedic Surgeons "Promising ACL surgery outcomes of aging athletes" 8/21/2018
[3] Societal and Economic Impact of Anterior Cruciate Ligament Tears (2013) 1715-1759 Journal of Bone and Joint Surgery Oct 2; 95(19) Mather, RC et al

Initial pre-clinical results indicate the CelGro® collagen rope has superior biomechanical properties and is capable of replacing hamstring grafts for ACL reconstruction. The CelGro® rope is designed to provide a novel off the shelf solution to a common problem in a multi-billion dollar global market.

Next Steps

The company is in the process of completing the pre-clinical study using CelGro® collagen rope for Anterior Cruciate Ligament (ACL) reconstruction and plans to provide a **full report of study results by 3Q CY2021.**

About CelGro®

Orthocell has secured 11 patent families covering its portfolio of breakthrough regenerative medicine products, comprising 110 separate patents/applications, of which 75 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 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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advancing tissue repair & regeneration

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.