CelGro® Nerve Repair AUS Regulatory Application Submitted

- **Australian TGA regulatory application for CelGro® for peripheral nerve repair** surgical applications submitted
- **Follows positive results from Orthocell's nerve repair study,** showing 96% of nerve repairs restored voluntary movement in affected muscles
- **CelGro®'s addressable market in nerve repair** is estimated to be worth **more than US$2 billion per annum**
- **Marketing and sale of CelGro® for nerve repair applications in Australia can commence** post TGA regulatory approval
- **Represents an important milestone in the commercialisation of CelGro® platform technology** for repair of bone, tendon, nerve and other soft tissue applications

Perth, Australia; 30 July 2020: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has completed a submission to the Australian Therapeutic Goods Administration (TGA) seeking approval for marketing its CelGro® product for peripheral nerve regeneration applications.

Orthocell's application for TGA approval of CelGro® in Australia follows its recent study results showing at 12 months after CelGro® surgery, voluntary muscle movement was restored in 96% of nerve repairs; and 86% of patients who required prescription pain medication, including opioid-based medications, were able to significantly reduce or stop their medication completely.

Orthocell Managing Director, Paul Anderson, said: *"This is a very important milestone for Orthocell as we continue to commercialize our collagen medical device platform and prepare for strategic entry into additional global markets. Our research to date indicates that CelGro® is a superior product for facilitating complex nerve regeneration, when compared to current alternatives, and we are optimistic in achieving regulatory clearance to enable Australian patients to access its life-changing impact.*

"We have seen incredible results so far. As an example, one of our quadriplegic patients progressed from having no strength in his arm and no movement in his fingers and thumb, to playing wheelchair rugby. This is extremely exciting for our researchers, doctors and patients, and we remain confident that we are on the cusp of a significant breakthrough for the repair of damaged nerves."

The nerve repair opportunity

Orthocell's clinical study results showed nerve repair using CelGro® resulted in improvements in muscle power at 12 months that were comparable to what would normally be expected at 24 months with other methods. The Company believes 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.

CelGro® facilitates tensionless repair of peripheral nerves and is of significant clinical interest to the surgical community (e.g. orthopaedics, hand and neurosurgery) because of the potential improvements in efficacy and efficiency of surgical procedures. Tensionless repair will reduce surgery time and the risk of additional trauma to soft tissue, caused by the use of sutures to join nerves and other tissues.

CelGro® addressable market in peripheral nerve repair
Orthocell has a clear commercialisation strategy for the CelGro® nerve regeneration indication and intends to leverage these results for regulatory submission in the US.

CelGro®'s addressable market in peripheral nerve repair is estimated to be worth more than US$2 billion per annum, with approximately 750,000 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.

In the US alone, more than 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 tubes that are secured in place with sutures.

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.

Release authorised by:
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
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

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® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro® and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro® is being readied for first approval in the US and AUS. The Company's other major focus is 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 **@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.