Orthocell commences nerve repair study

- **Orthocell commences a comparator study to support product marketing initiatives and international regulatory and reimbursement strategies**
- **This study is an integral part of Orthocell's comprehensive development program in nerve repair and regeneration**
- **Study to be undertaken in collaboration with Professor Bill Walsh, at University of New South Wales, with a target study completion Q1 2024**
- **Follows regulatory approval of Remplir for peripheral nerve repair in Australia in February 2022 and inclusion on the Prosthesis List for reimbursement in November 2022**
- **Remplir has the potential to become the leading device in the US in an addressable market estimated to be worth more than US$1.1 billion per annum[1]**
- **With recent appointments of key US-based surgeons Professor Christopher Dy and Professor David Brogan to the Medical and Scientific Advisory Board, Orthocell is ideally positioned to drive its innovative nerve repair medical device into international markets, including the USA**

Perth, Australia; 18 April 2023: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the commencement of a comparator study as part of a comprehensive pre-clinical and clinical development program in nerve repair and regeneration. The study provides information regarding mechanism of action that is not possible to collect in human clinical trials. The outcomes from the study will support product marketing initiatives and international regulatory approval and reimbursement strategies for its nerve repair device, Remplir.

Orthocell Managing Director, Paul Anderson, said: "*Remplir has shown, in previous studies, to be the superior product for nerve regeneration when compared to an FDA-approved comparator device. We are confident that the outcomes of this study will be consistent with the clinical performance of Remplir to date, and validate that Remplir is easier to use, reduces the need for sutures and results in more consistent and predictable return of muscle function.*"

"This study is an important next step in our international market access program with the potential to provide data demonstrating the impact and advantages of using Remplir over traditional nerve repair methods. Orthocell remains committed to providing patients access to this life changing treatment."

The study will be conducted using a well-established rat sciatic nerve injury model. The study is intended to evaluate safety, mechanism of action and product performance of Remplir, when used as a nerve wrap in peripheral nerve repair, compared to traditional repair methods. The repair of

[1] US addressable market estimate was developed by the Company using reports from US healthcare databases and referenced papers of studies conducted both within and outside the US.

surgically transected (severed) sciatic nerves will be evaluated in 72 rats across 3 study groups: Repair using suture only (control group), repair with Remplir, and repair with a Comparator. Nerve regeneration will be measured at 4, 8 and 24 weeks post-treatment. The key outcome measures include the performance of Remplir in facilitating high quality nerve regeneration, and restoration of motor and sensory function.

Surgical and Orthopaedic Research Laboratories

This preclinical study will be conducted by Professor Bill Walsh, Director of Surgical and Orthopaedic Research Laboratories (SORL) at the Prince of Wales Hospital in Sydney and the University of New South Wales. SORL is dedicated to developing biomedical, biotechnology and engineering solutions to improve clinical outcomes in injured and diseased states. Professor Walsh's research is at the interface between implanted materials and the connective tissues of the body as it relates to orthopaedic, vascular, plastic, and reconstructive surgery. Professor Walsh has extensive experience with preclinical studies for regulatory submissions and medical device development, with multiple commercialisation successes. The Company anticipates study completion in Q1 2024.

US addressable market in peripheral nerve repair

Orthocell believes Remplir has the potential to become the market-leading nerve repair device, with uptake driven by surgeons' preference for an easy-to-use, fit-for-purpose device that reduces the need for damaging sutures and provides an enhanced biological environment to facilitate nerve regeneration and better patient outcomes.

In a clinical study recently completed by the Company (ASX release 07 June 2022 – link), positive clinical data demonstrated that nerve repair with Remplir following injury to the spinal cord, brachial plexus and other nerves of the upper limbs consistently restores arm and hand function to previously paralysed limbs. Importantly, functional recovery of muscles controlled by the repaired nerve was observed in 85% (23 of 27) of nerve repairs at 24 months post-treatment. Without surgery, patients who suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents would not have regained normal use of their injured arm and hand. Remplir achieved regulatory approval in Australia in February 2002 and was included on the Prosthesis List for reimbursement in November 2022.

Remplir's US 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 Remplir completed each year[2]. The Company continues to work closely with US regulatory advisers to evaluate opportunities for expedited approval of alternative devices that may attract a high reimbursement value.

Medical Scientific Advisory Board

Orthocell recently appointed internationally recognised orthopaedic surgeons, Professor Christopher Dy and Professor David Brogan to its Medical Scientific Advisory Board. Professors Dy and Brogan, who specialise in nerve transfer and peripheral nerve repair, are based at Washington University and Barnes-Jewish Orthopedic Center, and among the US's leading academic research institutions and hospitals. These two highly qualified and experienced surgeons have been appointed to assist with

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clinical development and US market access for Orthocell's nerve repair medical device. With these additions to the specialist advisory team, Orthocell is ideally positioned to drive its market leading nerve repair medical device into the US market.

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Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include CelGro™, a collagen medical device which facilitates tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit www.orthocell.com 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.