Orthocell Successfully Completes all Nerve Repair Surgeries in Remplir™ US Market Authorisation Study

- **Orthocell successfully completes the first stage of its pivotal Remplir US market authorisation study. All nerve repair surgeries were performed, with no adverse events reported;**
- **Successful completion of all nerve surgeries enables the progression of the study to the final two stages in which safety and effectiveness of Remplir will be evaluated;**
- **The Study is expected to complete in Q3 CY24, the Company remains on track to submit its US 510(K) market authorisation application in Q4 CY24 and progression into sales soon thereafter;**
- **The US addressable market in peripheral nerve repair is estimated to be worth more than US$1.1 billion annually, with an estimated 700,000 procedures where Remplir could be used, completed each year;**
- **Orthocell is well funded for its current global market expansion strategy and beyond US market clearance for Remplir expected in Q1 CY25**

Perth, Australia; 25 March 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has successfully completed the first stage of the Remplir US 510(k) market authorisation nerve repair study. All surgical repairs of severed nerves were performed with no adverse events reported. Completion of the first stage enables the Company to progress with the final two stages of the study. The Company is on track to submit an application to the U.S Food and Drug Administration (FDA) for clearance to sell Remplir to surgeons in the US for use in peripheral nerve repair surgeries. Submission expected Q4 CY24.

Orthocell Managing Director, Paul Anderson, said: "*Remplir has been shown, in the previous pilot study, to be superior to the existing FDA-approved comparator device for nerve repair, restoring the sciatic nerve to its pre-injured state with no adverse reactions. Successful completion of stage one gives us confidence that the final two stages of the US market authorisation study will be consistent with the pilot study results, and the clinical performance of Remplir to date.*"

"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. We are excited to be at this important stage in the development of this product and remain committed to providing patients access to this life-changing treatment."

Non-executive director, Professor Fiona Wood, said: *"Results from the first stage of the study are extremely exciting as it de-risks the pathway to US market clearance and is another positive step towards making this life changing treatment accessible to patients worldwide."*

US 510k Study

The nerve repair study is being 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. The study, using a well-established rat sciatic nerve injury model, is designed to evaluate the safety and effectiveness of Remplir when used as a nerve wrap in peripheral nerve repair, compared to traditional repair methods.

In the final two stages of this study, the recovery of sensory and motor function (Stage 2) and quality of nerve regeneration (Stage 3), after surgical transection of sciatic nerves will be evaluated in 72 rats divided equally between 3 study groups: repair using suture only (control group), repair with Remplir, and repair with a Comparator device. Study outcomes will be assessed at 4-, 8-, and 24-weeks post-treatment. Key evaluations will include restoration of movement and sensitivity to heat and touch, as well as the quality of newly regenerated nerve tissue.

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.

A clinical study recently completed by the Company (ASX release 07 June 2022 – link) has provided promising data on the outcomes of nerve repair with Remplir following injury to the spinal cord, brachial plexus and other nerves of the upper limbs. Nerve repair with Remplir consistently resulted in recovery of arm and hand movement in 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 nerve repair surgery, these 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.

The US addressable market in peripheral nerve repair is estimated to be worth more than US$1.1 billion annually, with an estimated 700,000 procedures where Remplir could be used, completed each year[1].

About Surgical and Orthopaedic Research Laboratories

Surgical and Orthopaedic Research Laboratories (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.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

[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.

ortho·cell
advancing tissue repair & regeneration

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About Orthocell Limited

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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™ platform of collagen medical devices which facilitate 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 and FDA engagement to confirm the path to the US market and prepare for partnering discussions.

For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter **@Orthocelllltd** 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.