Orthocell Submits U.S. FDA Regulatory Application to Commercially Distribute Remplir™ into the US$1.6 billion U.S. market – Clearance Expected late March or early April 2025

- **Orthocell has submitted its U.S. FDA 510(k) regulatory application for clearance to commercially distribute Remplir™ into the US$1.6 billion[1] U.S. market**
- **Submission follows successful completion of the Remplir regulatory study which met all endpoints and provided the key data to support a U.S. FDA 510(k) clearance**
- **Based on the expected 90 calendar day review process for U.S. FDA 510(k) submissions and allowing for the festive period closures, Orthocell anticipates market clearance for Remplir late March or early April 2025**
- **The Company is well advanced in its commercial launch preparations with the recent appointment of U.S. sales and medical affairs executives to drive the market launch and sales immediately post clearance**
- **Remplir is already approved and selling in the Australian, New Zealand and Singapore markets with rapidly growing sales, and an increasing number of surgeons using and endorsing its unique repair qualities in clinical practice**
- **Orthocell has a strong balance sheet with circa $33 million[2] in cash to drive the U.S. market launch, along with accelerating its regulatory program into other jurisdictions, including the key U.S. market, Canada, U.K., Europe and other ASEAN markets**

Perth, Australia; 19 December 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the submission of its U.S. FDA 510(k) regulatory application ("Regulatory Submission") for clearance to commercially distribute Remplir™ into the US$1.6 billion[1] U.S. nerve repair market. The Regulatory Submission formally kicks off the U.S. FDA 90 calendar day review process with US clearance anticipated in late March or early April 2025 and commercial distribution to commence soon thereafter.

Orthocell CEO and MD, Paul Anderson, said: *"We are thrilled to submit our U.S. 510(k) regulatory application following successful pre-submission meetings with the FDA and completion of our pivotal Regulatory Study. We believe Remplir is redefining the nerve repair market and leading the way in successful nerve repair surgery. With a strong balance sheet, and U.S. sales and medical affairs team leads in place, we are now resolutely focused on preparing for launch and to commence selling Remplir in the largest healthcare market in the world."*

Submission of the U.S. FDA 510(k) regulatory application follows the successful completion of the Remplir 510(k) nerve repair study ("U.S. Regulatory Study" of "the Study"), demonstrating that Remplir is safe and effective for use in surgical repair of peripheral nerves, with outcomes comparable to the FDA-cleared comparator device. The positive findings, highlighting the performance of Remplir in facilitating nerve regeneration, provides key evidence to support a claim of *substantial equivalence*, which is a critical component of a 510(k) regulatory application.

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[1] USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

[2] As at 30th November, 2024

The positive outcomes from the U.S. Regulatory Study and previously published clinical data, indicating consistent and predictable return of upper arm and hand function following nerve repair with Remplir, will assist the Company in driving into the U.S. market. Achieving regulatory clearance for Remplir in the US nerve repair market, estimated to be worth in excess of U.S. $1.6 billion[1] per annum and growing, represents a significant opportunity for the Company's future growth.

The Company is well advanced in its commercial launch preparations with the recent appointment of U.S. sales and medical affairs executives, commencement of discussions with potential distributors, and engagement of a panel of U.S. Key Opinion Leaders (KOLs). With circa $33 million[2] in cash and no debt, Orthocell is well-positioned to drive the market launch and sales of Remplir following anticipated market clearance in late March or early April 2025.

Remplir – Redefining Nerve Repair

Orthocell believes Remplir is redefining the global nerve repair market and rapidly becoming an important element in nerve repair surgery to return function to paralysed upper limbs. Remplir nerve wrap is a sterile, implantable, biocompatible, resorbable, collagen membrane intended for use in the management of peripheral nerve injuries. Remplir's ability to integrate into nerve tissue, with an optimal resorption profile and no adverse reactions, provides ideal conditions for nerve regeneration. These properties, combined with Remplir's excellent handling characteristics, will empower surgeons to perform these challenging surgical procedures and ultimately improve the lives of more patients suffering from complex spinal cord or traumatic nerve injuries.

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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 a 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), New Zealand (WAND), UK (UKCA Mark) 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 **@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.