Orthocell submits Singapore Regulatory Application for Remplir™

- **Orthocell's global expansion strategy for its market leading peripheral nerve repair product Remplir, continues to build with the submission of its regulatory application to the Health Services Authority of Singapore for approval to market and sell the Product.**
- **Remplir is now generating and growing revenue in Australia, pending application for use in the US, and Singapore is expected to be the 3rd country in which Remplir is available for sale.**
- **US approvals process progressing according to plan with the Remplir US 510k regulatory study on track for completion and data read out in Q3 CY24, with US regulatory application on track for submission in Q4 CY24 and approval expected shortly thereafter.**
- **With an experienced senior, multinational advisory team and strong cash position, Orthocell is ideally positioned to drive Remplir into the global markets.**

Perth, Australia; 13 February 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") today announced its application to market and sell its leading peripheral nerve repair product Remplir in Singapore, has been accepted for review by Health Services Authority of Singapore (HSA). HSA is the Singaporean Ministry of Health's body responsible for regulating the importation, manufacture, export, and supply of medical devices. Evaluation of Orthocell's application by HSA is already in progress.

Orthocell Managing Director, Paul Anderson, said**:** *"We are delighted to announce our Singapore market regulatory application. This is another significant milestone in our expansion strategy and a testament to our team's efforts to gain approval of Remplir for nerve repair in key global markets. Singapore is an important market and a stepping stone to the very large and attractive ASEAN targets. Once approved, it will be the third country in which Remplir is available for sale, with US regulatory application, a key focus of the Company, on track for submission Q4 CY24."*

The Company's exclusive distributor of Remplir across Australia and New Zealand, Device Technologies (DVT), continues to drive product adoption in these markets, with **100+ orthopaedic and plastic surgeons** now using Remplir in peripheral nerve repair surgeries, from facial to upper and lower limb nerves.

Orthocell is well positioned to drive Remplir into global markets, with a strong cash position, focussed regulatory program targeting multiple strategic markets and the pivotal nerve repair study for US regulatory approval on track for completion in 2024.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

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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.