

Orthocell Achieves Major Milestone with First Sales of Remplir™ in Singapore

- Orthocell continues its rapid commercialisation pathway with first sales of its leading peripheral nerve repair device Remplir™ in Singapore
- Remplir is now being sold in Singapore, Australia and New Zealand, where sales continue to grow with an increasing number of surgeons using and endorsing its unique repair qualities
- Initial Remplir sales are well ahead of a planned Singapore market launch in Q1 CY25, demonstrating the quality of the Remplir product and the strength of the Company's distribution partner Device Technologies Asia
- Singapore is a strategic jurisdiction, both as a destination for sophisticated medical treatments in the region and as a regulatory gateway to other substantial ASEAN markets, in a global nerve repair market estimated to exceed US\$3.5 billion¹.
- Commercialisation in Singapore has occurred rapidly with regulatory approval received in October 24, through to first sales achieved in December 24
- The Company's commitment to global expansion and revenue generation in new markets continues with US FDA clearance expected in the first quarter of 2025 and commencement of sales into the world's largest healthcare market soon thereafter
- Orthocell has a strong balance sheet with circa \$33 million² in cash to successfully launch Remplir in Singapore and United States, along with accelerating its regulatory program into other jurisdictions, including the Canada, U.K., Europe and other ASEAN markets

Perth, Australia; 12 December 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce first orders for its leading peripheral nerve repair device Remplir™ from its recently appointed exclusive distribution partner Device Technologies Asia ("DVT Asia"). The initial order has been received ahead of a planned Singapore market launch in Q1 CY25, demonstrating the quality of the Remplir product. DVT Asia is well placed to gain sales traction in this strategic jurisdiction, having already established relationships with target customers including leading plastic reconstructive and orthopaedic surgeons at high quality surgical centres.

Orthocell CEO and MD, Paul Anderson, said: "We are delighted to report first sales to DVT Asia earlier than expected. Device Technologies is our chosen distribution partner in Australia, New Zealand and Singapore and have moved quickly to begin selling our leading nerve repair product Remplir in Singapore. We expect additional sales, revenue growth and surgeon adoption of Remplir to accelerate in the new year."

Sales of Remplir has grown quickly in the Australian and New Zealand markets, with an increasing number of surgeons using and endorsing its unique repair qualities. Singapore represents the first major international market launch outside the existing markets of Australia and New Zealand.

The rapid progression from Remplir's recent regulatory approval from the Health Sciences Authority (HSA) in Singapore, to signing the distribution agreement with DVT Asia, to early sales is further validation of the Company's commitment to global expansion and revenue generation in new markets. DVT Asia will market

¹ Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

² As at 30th November, 2024

and distribute Remplir for use in the surgical repair of peripheral nerves across Singapore, undertaking medical education, targeted promotion activities and initiating sales, as well as expanding the network of referring plastic and orthopaedic surgeons.

With circa \$33 million in cash and no debt, Orthocell is ideally positioned to successfully launch Remplir in Singapore and other key markets including United States, South East Asia, Canada and the EU/UK. Importantly, the Company remains on schedule to submit its Remplir US 510(K) application in Q4 CY24, with progression into U.S. FDA clearance and commercial distribution soon thereafter.

About Device Technologies Asia

Since 1992, DVT Asia has remained committed to providing healthcare professionals with access to innovative, high-quality medical devices and solutions from around the world. DVT Asia's vision is to enable superior health outcomes by connecting healthcare professionals with the finest medical technologies and supplies in the market.

The Device Technologies Group continues to grow, with over 200+ trusted brands and 1,000 highly skilled staff across Australia, New Zealand and Asia. All products distributed by Device Technologies are compliant with quality and regulatory requirements, with in-servicing, education and ongoing clinical and technical support provided as part of the trusted partnership between Device Technologies' staff and healthcare professionals. For more information, visit devicetechnologies.asia.

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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 its 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.