

Orthocell Submits Thailand Regulatory Application to Commence Sales of Remplir™ into the US\$84million Thai market

- Orthocell continues its global expansion push with submission of a regulatory application to the FDA of Thailand for the sale of Remplir™ in this significant and growing US\$84million¹ market. Approval is expected in Q3 CY2025
- Submission follows strong sales and continued record revenue growth in existing markets for Remplir in Australia, New Zealand and Singapore
- Rapid transition from approval to first sales in Singapore underpins Orthocell's accelerated expansion into the Asia Pacific region. The Company is now evaluating market opportunities in Hong Kong, Taiwan, Vietnam, Indonesia and the Philippines
- Orthocell also remains on track to gain US FDA 510(k) regulatory clearance to commercially distribute Remplir into the critical US\$1.6 billion² US market, with approval expected in March / April 2025
- Approval for Remplir in the US\$75million³ Canadian market is expected in the second half of 2025
- Accelerated global expansion will significantly increase the revenue opportunity for the Company, targeting a 20% share of the US\$3.2 billion⁴ of value in selected markets
- The Company has a strong balance sheet with circa \$33 million⁵ cash at bank and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets

Perth, Australia; 21 February 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has submitted an application to the Thai Food and Drug administration (Thai FDA) to sell its leading nerve repair product Remplir™ into the US\$84 million¹ Thailand nerve repair market. The submission leverages an expedited registration pathway available for medical devices already approved by the Health Sciences Authority (HSA) in Singapore. The expedited pathway reduces the review time by half and at a substantial reduction in the registration cost. Evaluation of Orthocell's application to the Thai FDA is now in progress with clearance expected in Q3 2025.

Like Singapore, Thailand has a high quality, well-developed healthcare system, boosted by a strong medical tourism sector. Thailand, in addition to Singapore and Malaysia, is a major healthcare hub in the Asia Pacific region and is actively adopting advanced technologies and treatment options. Orthocell is evaluating other potential markets in the region including Taiwan, Vietnam, Indonesia and Philippines. Hong Kong is also an attractive market in the region as a recognised leader in medical services across Asia.

Remplir is a collagen wrap used in nerve repair surgery to assist surgeons to improve outcomes in the repair and regeneration of damaged nerves. Remplir is approved for sale in Australia, New Zealand and Singapore and is pending approval in the US, Canada and Thailand in CY2025. Remplir has gained excellent sales traction since its Australian market launch in November 2022 and the Company has achieved three consecutive

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

² USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

³ Canada nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

⁴ Company estimate of addressable market size for Remplir (AUS, SGP, USA, CAN, THA, EU/UK & BRZ). Sources include iData Research Inc and other publicly available market research reports and published literature.

⁵ Cash at 17th January, 2025.

quarters of record revenue. There are ~180 orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries across Australia, New Zealand and Singapore.

As previously announced, preparations for the US market launch are well underway ahead of market clearance from the US FDA, expected late March or early April 2025, with sales to commence shortly thereafter. Orthocell also recently submitted a regulatory application to Health Canada to complement market launch in the US. Approval in Canada is expected in the second half of 2025.

The Company is also accelerating its plans to enter a number of other key markets across CY2025 including United Kingdom, European Union and Brazil, with other Latin American and Asia Pacific markets under evaluation. The UK and EU regulatory submissions are targeted for the September Quarter '25, followed by Brazil in the December Quarter '25.

The Company has a strong balance sheet with circa AU\$33 million⁵ cash at bank and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets. The combined global market opportunity for Remplir is estimated to be approximately US\$3.2 billion⁴ (circa A\$5 billion) with Orthocell targeting a 20% market share. Effective expansion into other markets would see an increase in these projections, demonstrating significant near-term growth potential for the Company.

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, and is distributed globally by BioHorizons Implant Systems Inc. Striate+™ is cleared for use in the US(510k), Canada (MDL), Australia (ARTG), New Zealand (WAND), the UK (UKCA Mark) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies. 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.