# Orthocell Submits Regulatory Application to Commence Sales of Remplir™ in Hong Kong

- **Orthocell continues its commercial expansion program in Asia for its nerve repair product Remplir™ with submission of a regulatory application to the Hong Kong Department of Health's Medical Device Division. Approval to commence sales is expected in Q4 CY2025**
- **Submission follows strong sales growth in existing markets for Remplir in Australia, New Zealand and Singapore, and the recent landmark US 510(k) clearance to commence commercial distribution in the US$1.6 billion[1] US market**
- **Rapid transition from approval to first sales in Singapore underpins Orthocell's accelerated expansion into the Asia Pacific region. The Company is expecting approval in the US$84million[2] Thai market in Q2 CY2025 and is now evaluating market opportunities in Taiwan, Vietnam, Indonesia and the Philippines**
- **Accelerated global expansion will significantly increase the revenue opportunity for the Company, targeting a 20% share of the US$3.2 billion[3] of value in selected markets**
- **The Company has a strong balance sheet with circa $32 million[4] cash at bank and is very well funded to continue to broaden its commercial footprint and grow revenues in new and existing markets**

**Perth, Australia; 10 April 2025:** Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has submitted an application to the Department of Health's Medical Device Division (MDD) in Hong Kong to sell its leading nerve repair product Remplir™. Hong Kong is an attractive market in the region as a recognised leader in medical services across Asia. Approval to commence sales is expected in Q4 CY2025.

The application to register Remplir in Hong Kong complements the Asian regulatory program for Remplir, with approval already achieved in Singapore, approval expected in Thailand in Q2 CY2025, and market opportunities in Taiwan, Vietnam, Indonesia and the Philippines under review.

**Orthocell CEO and MD, Paul Anderson, said: "**Building on our early success in Singapore, we see an excellent opportunity for Remplir throughout Asian markets. We'll continue to approach these markets using experienced on-the-ground distributors to market the product direct to customers, like we have done in Singapore. Not only does the distributor model provide a rapid path to sales, it is also cost efficient enabling the Company to focus on the market launch of Remplir into the globally significant US$1.6 billion[1] US nerve repair market."

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, Singapore and the USA. Remplir has gained excellent sales traction since its Australian market launch in November 2022 and the Company has achieved three consecutive 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.

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

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

[3] 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.

[4] Cash at bank as at 26th March, 2025.

The Company has a strong balance sheet with circa AU$32 million[3] 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 market opportunity for Remplir in selected markets is estimated to be approximately US$3.2 billion[3] (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.

For more information, please contact:


## General & Investor enquiries

**Paul Anderson**
**Orthocell Limited**
**Managing Director**
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

## Media enquiries

**Haley Chartres**
**H^CK Director**

P: +61 423 139 163
E: haley@hck.digital


## About Orthocell Limited

**ACN 118 879 135**
**Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia**

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 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.