Orthocell Receives Regulatory Approval to Commence Sales of Remplir™ in the Strategically Important Hong Kong Market

- **Orthocell has been granted a licence by the Hong Kong Department of Health's Medical Device Division to commence sales of Remplir™ into the Hong Kong nerve repair market.**
- **Approval received well ahead of initial expectations of 4Q CY25 following regulatory submission in April 2025. Rapid turnaround a testament to the product quality and clinical data.**
- **Hong Kong is considered a strategically valuable APEC addition to the Remplir global footprint with the country recognised as a leader in medical services across Asia.**
- **Approval builds on significant recent momentum of regulatory approvals for Remplir in the US, Thailand and Canada in April 2025, in addition to Australia, New Zealand and Singapore.**
- **Orthocell ultimately targeting Total Addressable Market ("TAM") in selected jurisdictions in excess of US$3.5 billion[1], with the current TAM in markets where Remplir is approved already equating to US$1.8 Billion[2].**
- **Incremental markets outside of the US, including Hong Kong, to be serviced using external specialist distributors with minimal additional internal resources required.**
- **Internal resources remain focused on the Remplir rollout in the US$1.6 Billion US market[3], with in-country representatives making significant progress towards imminent first US sales.**
- **Existing cash reserves of $31.7 million (as at 31 March 2025) see the Company fully funded for the Remplir global roll out.**

Perth, Australia; 12 May 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has received a license from the Hong Kong Department of Health's Medical Device Division for its flagship nerve repair product Remplir™. The license, originally expected to be granted in 4Q CY25, was received approximately one month following the regulatory submission on 10 April 2025 demonstrating the quality of the product, the clinical data, and its growing global recognition. The Company can now commence sales of Remplir into the Hong Kong nerve repair market.

Hong Kong is considered a strategically valuable market in the APEC region as a recognised leader in medical services across Asia. Orthocell has now built a significant portfolio of Remplir regulatory approvals in the region with Australia, New Zealand, Singapore and Thailand already in place together with approvals in the US and Canada. In aggregate, the markets in which Remplir is approved represents a TAM of approximately US$1.8 billion[2]. Further regulatory applications for the EU and UK are on track to be submitted in the next 6-12 months.

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

[2] Company estimate of addressable market size for Remplir (AUS, NZ, SGP, USA, THA, CAN). Sources include iData Research Inc and other publicly available market research reports and published literature

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

Orthocell intends to appoint a local on-the-ground specialist distributor to drive sales in Hong Kong. The Company has built significant experience working with local distributors across both its Remplir and Striate+ products in multiple global jurisdictions and is well placed to appoint an appropriate distributor for Remplir in the Hong Kong market.

Orthocell CEO and MD, Paul Anderson, said: "We are delighted to receive approval for Remplir in Hong Kong just one month after lodging our application. The Hong Kong authorities have the right to take up to 12 months to assess submissions, so to turn it around so quickly is a testament to our product quality and clinical data.

"We are now building a strategically valuable portfolio of approvals for Remplir spanning the Asia Pacific region and North America. We believe each additional country adds to the overall strategic value of our product portfolio.

"We've experienced rapid growth in 2025 in the number of countries in which Remplir is approved and our focus is moving towards converting those approvals into sales.

"We'll continue to be smart in how we go about driving sales in these markets. Our strategy is to focus the bulk of our internal resources on our largest potential market, the US, while using specialist in-country distributors in other markets."

Remplir is a collagen wrap used in nerve repair surgery to assist surgeons to improve outcomes in the repair and regeneration of damaged nerves. Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US$3.5 billion[1] with an estimated ~2.0M peripheral nerve repairs performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan, Hong Kong and Thailand.

The Company has a strong balance sheet with A$31.7 million cash at bank as at 31 March 2025 and no debt, and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets.

Release authorised by:
Paul Anderson
Orthocell Ltd CEO and MD

For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited
CEO and MD
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

Investor enquiries

Shaun Duffy
Vector Advisers

P: +61 404 094 384
E: sduffy@vectoradvisors.au

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 the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed its first 12 US distributors, with first sales expected to follow shortly. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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.