Orthocell Receives Regulatory Approval to Commence Sales of Remplir™ in US$84 million Thai market

- **Orthocell has been granted a licence by the Food and Drug Administration ("FDA") of Thailand to commence sales of Remplir™ into the significant and growing US$84 million[1] Thai nerve repair market.**
- **Remplir is now approved in the US, Australia, New Zealand, Singapore and Thailand, which equates to a significant market opportunity of $1.7 billion[2] and with further jurisdictions planned and pending.**
- **Orthocell has achieved strong revenue growth over the last 12 months and with this continued growth in existing markets and recent approval for Remplir in the US and Thailand, the Company expects a step change in revenue once sales traction is achieved in these new markets.**
- **Thai approval received far sooner than expected and follows regulatory submission in February 2025 having leveraged an expedited registration pathway available for medical devices already approved by the Health Sciences Authority (HSA) in Singapore.**
- **Thailand is a sophisticated market which has a high quality, well-developed healthcare system, boosted by a strong medical tourism sector and is an important growth market for Remplir**
- **Orthocell plans to partner with an exclusive distributor in Thailand and expects first sales from this region in the second half of 2025.**
- **Existing cash reserves of $31.7 million (as at 31 March 2025) see the Company fully funded for the growing global roll out of product portfolio.**

Perth, Australia; 28 April 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has received a license from the FDA of Thailand for its flagship nerve repair product Remplir™. The license clears the way for commercial distribution of Remplir into Thailand which has a high quality, well-developed healthcare system, boosted by a strong medical tourism sector. The Thai nerve repair market has an estimated value of US$84 million.

Orthocell leveraged an expedited registration pathway available for medical devices already approved by the Health Sciences Authority (HSA) in Singapore, which Orthocell received in October 2024. The expedited pathway significantly reduced the review time and at a substantial reduction in the registration cost and demonstrates the Company's ability to rapidly push into the wider Asian region.

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

[1] Estimated using referenced papers from both US and OUS databases and studies

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

Orthocell CEO and MD, Paul Anderson, said: "We are delighted to receive regulatory approval for Remplir in Thailand far sooner than we expected which shows the quality of the product and our clinical data. Thailand is an influential medical market in the Asian region and the second largest market for Remplir, after the US, that we have received approval for. This approval significantly enhances our Asia Pacific presence for Remplir with approvals already having been received in Australia, Singapore and New Zealand. This is in addition to the US FDA clearance received earlier this month."

"We continue to be well capitalised to roll out our expansion plans for both Striate+ and Remplir in the growing number of jurisdictions that we have received approvals throughout the world. The growing global footprint we are experiencing is adding a step change in value to our product portfolio with each additional regulatory approval achieved."

"All products will be manufactured at our Perth facility to deliver into these markets."

Orthocell is evaluating other potential markets in the Asia Pacific 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. In addition to the approved markets discussed above, regulatory applications for the EU and UK are on track to be submitted in the next 6-12 months and approval is currently pending in Canada.

Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US$3.5 billion with an estimated ~2.0M peripheral nerve repairs performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan and Thailand[3].

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.

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[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.

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 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 four 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.