Orthocell US Remplir™ Sales Rollout Gains Pace with 12 Distributors Now Appointed Covering 21 States

- **Orthocell has now appointed 12 US distributors of its flagship nerve repair product Remplir™.**
- **Distributor appointments are well ahead of expectations with the Company previously advising it was targeting 10 distributors by 30 June 2025.**
- **Distributors are experienced nerve specialists with operations collectively spanning 21 US states. They hold direct relationships with surgeons and hospitals within each geographic region and represent the most efficient path to market in the US.**
- **Orthocell has made rapid progress in building distributor numbers post receipt of US FDA 510(k) clearance for Remplir on 3 April 2025 FDA 510(k) due to extensive pre-launch activities in the US by the Company's in-house sales, marketing and medical affairs executives.**
- **The rapid increase in Distributor appointments demonstrates the quality of the Remplir product and distributor confidence in being able to generate strong sales. This expanded sales infrastructure is expected to drive a step change in revenue for the Company moving forward.**
- **Consistent with the Company's sales strategy, the distributor network will be managed by an in-house team of sales directors led by the US Vice President of Sales with a further four territory managers to support sales activities.**
- **Internal resources remain focused on the Remplir sales rollout and outreach to additional distributors, with first US sales now imminent within a US$1.6 Billion[1] market.**
- **Existing cash reserves of $31.7 million (as at 31 March 2025) see the Company fully funded for the US roll out.**

Perth, Australia; 09 May 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has added a further eight distributors for its flagship nerve repair product Remplir™, taking the total number of US distributors signed to 12. The signing of distributors has progressed well ahead of expectations with the Company previously advising it was targeting 10 distributors in place by 30 June 2025. The rapid signing of these new distributors is a testament to the quality of Remplir and the Distributor's belief in being able to generate strong sales for the product in the US.

Following these new appointments, Orthocell's distributor group collectively covers 21 US states. The distributor relationships are non-exclusive and the Company will continue to sign additional distributors to expand access to the US market. Orthocell's distributors will operate on a commission-based structure typical of US medical product distributor relationships, which is a cost-effective operating model for Orthocell.

US distributors generally focus on specialist product lines within a given medical field in local geographic regions where they hold trusted relationships with surgeons and hospitals. The distributors will market and distribute Remplir for use in the surgical repair of peripheral nerves across their respective geographic regions, undertaking medical education, targeted promotion activities and initiating sales, as well as expanding the network of referring plastic and orthopaedic surgeons.

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

Orthocell's internal management resources remain focused on the rollout of Remplir in the Company's largest market, the US. In addition to expanding the portfolio of distributors, Orthocell's on-the-ground sales and marketing and medical education executives are focused on training sales reps, submitting proposals to key hospitals to become approved suppliers, expanding a key opinion leader (KOL) panel and undertaking product roadshows in preparation for imminent first product use. Orthocell is well positioned to achieve first sales of Remplir in the US$1.6 billion nerve repair market in the near term.

Orthocell CEO and MD, Paul Anderson, said: "It's very pleasing to see such rapid progress on the expansion of our US distributor network so soon after receiving US FDA clearance in April. We're well ahead of the targets we had set ourselves and expect that to translate to first US Remplir sales this quarter.

"Our US team has been working tirelessly leading up to the product launch and we're confident we have the right strategy to drive market penetration of the US. For us, that means a combination of experienced internal employees complemented by a portfolio of distributors who have active sales channels to reach and engage our customers. We expect to grow our portfolio of distributors too."

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 US, Remplir is currently approved for sale in Australia, New Zealand, Thailand and Canada. Regulatory applications for the EU and UK are on track to be submitted in the next 6-12 months. 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[2] performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan 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.

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[2] Company estimate of addressable market size for Remplir (AUS, SGP, USA, EU/UK, CAN, BRZ, JAP & THA). 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, is approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group in those markets. The Company's flagship nerve repair product is also approved in the US, Canada and Thailand. 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.