

Orthocell Appoints its First Four US Remplir™ Distributors with Initial Sales in the US Expected Near Term

- Orthocell has appointed its first four US distributors of its flagship nerve repair product Remplir™, with first sales expected to follow shortly thereafter.
- Appointments quickly follow receipt of US FDA 510(k) clearance for Remplir on 3 April 2025 enabling the commencement of commercial distribution into the globally significant US\$1.6 billion¹ nerve repair market.
- Distributors are experienced nerve specialists operating in Michigan, Virginia, Colorado and Indiana states.
- Prompt appointment post FDA 510(k) clearance is a result of the extensive pre-launch activities undertaken in the US by Orthocell's in-house Sales, Marketing and Medical Affairs executives.
- The Company is targeting to appoint ~10 US distributors by 30 June 2025 in select regions to accelerate the US Remplir rollout and grow sales in the market quickly. These appointments would account for representation in ~25 states.
- Distributor model represents the most efficient path to market in the US while also providing a cost-effective operating structure for Orthocell. Distributor network to be managed by an in-house team of Sales Directors led by the US Vice President of Sales with a further 4 territory managers to support sales activities.
- Existing cash reserves of \$31.7 million (as at 31 March 2025) see the Company fully funded for the US roll out

Perth, Australia; 23 April 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has appointed its first four US distributors of its flagship nerve repair product Remplir™. Remplir received US FDA 510(k) clearance on 3 April 2025 allowing for its immediate commercial distribution into the US. The Company is now moving quickly to capitalise on the US approval and commence sales into the world's biggest nerve repair market which is expected to materially increase revenue for the Company.

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. Orthocell's first four distributors have a speciality in nerve repair with relationships in Michigan, Virginia, Colorado and Indiana.

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. Orthocell's distributors will operate on a commission-based structure typical of US medical product distributor relationships.

Orthocell is well positioned to achieve first sales of Remplir into this US\$1.6 billion nerve repair market, having already undertaken extensive pre-launch activities on the expectation that FDA 510(k) clearance would be successfully received. Manufacturing and logistics requirements are in place and significant Remplir inventory has been built up to meet US sales requirements.

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

Orthocell CEO and MD, Paul Anderson, said: “We have been working closely with a number of distributors in the United States in advance of our recently received FDA 510(k) clearance and welcome them on board as our first partners in the US. We are looking forward to our distributor network helping us to drive Remplir sales, and as a company, we are primed and ready to deliver Remplir into the US.”

“The distributor model is an excellent fit for us in the US. It allows us to partner with distributors that have existing strong relationships and established sales channels with both surgeons and hospitals which means we only need a small, but experienced, on-the-ground team of in-house employees. We are expecting to have ~10 distributors in place by the end of our financial year which would account for representation in approximately 25 states.”

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 and Singapore, with pending approvals in Canada and Thailand within the next 6 months. 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 repairs³ 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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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 US FDA (510k), Australia (ARTG), New Zealand (WAND), UK (UKCA Mark) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market. 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](https://twitter.com/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.

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