Landmark US FDA 510(k) Clearance for Orthocell's Flagship Remplir™ Nerve Repair Product Opens up US$1.6 Billion US Market

- **Orthocell has received US FDA 510(k) clearance for Remplir™, its flagship nerve repair product, enabling the Company to commence commercial distribution into the globally significant US$1.6 billion[1] nerve repair market**
- **Company-defining Remplir regulatory clearance is expected to drive a significant step change in revenue and pathway to breakeven and profitability within a foreseeable timeframe**
- **Orthocell is well placed to generate first US sales with logistics and sales pathways already established, including the November 2024 appointments of experienced US-based marketing, sales and medical education executives**
- **Orthocell is prepared for the expected step change in revenue from the US, with annual medical device manufacturing capacity for 100,000 units in place, and capability for further modularised low capital manufacturing expansion**
- **Orthocell owns and controls the manufacturing process, has no debt and no royalty liabilities, so all margins associated with the product are retained**
- **Existing cash reserves of ~$32 million[2] see the Company fully funded for the US roll out, the continued broadening of its commercial footprint and growth of revenues in existing and new markets.**

Perth, Australia; 04 April 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce that the US Food and Drug Administration (FDA) has granted regulatory clearance under the 510(k) pathway for the Company's nerve repair product, Remplir, enabling the commencement of sales in the US 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.

This is a landmark development for the Company and paves the way for commercial distribution of Remplir into the world's largest nerve repair market, at an estimated total addressable market value of US$1.6 billion[1] (circa A$2.5 billion). Orthocell expects the US roll out of Remplir to be an inflection point in its commercialisation path and the catalyst to drive the Company towards profitability within a foreseeable timeframe.

Orthocell CEO and MD, Paul Anderson, said: "I'm delighted to announce we have received FDA clearance for our market-leading nerve repair product. We have been preparing in advance for this pivotal milestone, ramping up production from our facility in Perth and we have significant levels of inventory in place to deliver on early sales orders.

Our sales, marketing and education team have made great progress identifying key opinion leaders, reputable reference sites and, most importantly, the distributors that we will work with to get Remplir into surgeons' hands.

We expect strong product adoption in the US, having experienced rapid sales traction in existing markets driven by the excellent feedback from surgeons in Australia, New Zealand and Singapore."

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

[2] Cash at bank as at 26th March, 2025

Remplir product delivered to the US will be manufactured at Orthocell's certified Good Manufacturing Practice facility in Perth, Western Australia, using the Company's proprietary SMRT™ manufacturing technology developed in conjunction with Professor Minghao Zheng and the University of Western Australia. The facility has capacity to produce 100,000 collagen medical devices per annum and does not require any material capital expenditure from Orthocell to support the initial US roll out.

Existing competitor device penetration into the nerve reconstruction surgical market is estimated at 10%, therefore Remplir does not need to replace an existing dominant incumbent product in order to gain meaningful market share.

The US commercial strategy will be a combination of an internal team led by Vice Presidents of Sales, Marketing and Medical Affairs, supported by Territory Managers who, in turn, will manage a network of external distributors. The US executive leadership team, with detailed industry knowledge and established clinical and commercial relationships, has been in place for several months with a focus on:

- Strengthening the panel of key opinion leaders
- Establishing highly regarded hospital reference sites
- Regional distributor network, with a target of 12 engaged within 6-12 months.

Delivery of sales within the US will be supported by an on-the-ground logistics partner with a central warehouse facility to coordinate order fulfillment and customer service. Logistics into the market is straightforward, as Remplir is lightweight, has a shelf-life of 3 years and is therefore easily transported by air freight.

Remplir is currently approved for sale in Australia, New Zealand and Singapore, with pending approvals in Canada and Thailand in 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 repairs[3] performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan and Thailand.

The company will conduct a webinar to provide further details in respect of this announcement, the details of which have been separately announced to the ASX.

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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 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, is 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.