Outstanding Early Sales Growth For Remplir™ Drives Orthocell to Accelerate Global Commercial Expansion

-5 New Country Regulatory Submissions Planned in 2025-

- **On the back of outstanding early sales traction for Remplir™ in Australia, New Zealand and Singapore, as evidenced by a third consecutive quarter of record revenue, Orthocell is accelerating its global expansion into multiple key jurisdictions**
- **As announced, Orthocell has recently submitted its US FDA 510(k) regulatory application for clearance to commercially distribute Remplir into the US$1.6 billion[1] U.S. market, with approval expected in March / April 2025**
- **The Company will now accelerate its plans to enter a number of other key markets across CY2025 including Canada, Thailand, United Kingdom, European Union and Brazil, with other ASEAN and Latin American markets also under evaluation**
- **The Canadian regulatory submission is well advanced and is expected to be lodged shortly**
- **Additional regulatory submissions include:**
  - **Thailand targeted for the March Quarter 25**
  - **UK and EU targeted for the September Quarter 25**
  - **Brazil targeted for the December Quarter 25**
- **The accelerated global expansion will significantly increase the revenue opportunity for the Company, targeting a 20% share of the US$3.2 billion[2] market**
- **The Company has a strong balance sheet with circa $33 million[3] cash at bank and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets**

Perth, Australia; 22 January 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce that, on the back of outstanding early sales traction, the market expansion of Remplir™ will be accelerated ahead of US FDA clearance expected in March/April 2025. A further five applications across Canada, Thailand, the United Kingdom, the European Union and Brazil are in progress for 2025. Expansion into these markets will significantly increase the revenue opportunity for the Company to circa US$3.2 billion, where the Company's is targeting a 20% market share.

Remplir is a collagen wrap used in nerve repair surgery and is intended to assist surgeons to improve outcomes in the repair and regeneration of damaged nerves. Remplir is approved for sale in Australia, New Zealand and Singapore and distributed by Device Technologies (DVT), a large and highly regarded distributor of high-quality medical devices. Remplir's unique qualities, allowing less suturing, creation of an optimal healing microenvironment and facilitation of free gliding in the repair site during the critical healing period, has contributed to the excellent traction the product has gained since the Australian market launch in November 2022. There are ~160 orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries, from facial nerves to upper and lower limb nerves, across Australia, New Zealand and Singapore.

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

[2] 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.

[3] Cash at 17th January, 2025

Importantly, the Company remains on track to achieve clearance to commercially distribute Remplir into the USA, the largest and highest value nerve repair market, estimated to be worth ~US$1.6 billion U.S. per annum. Approval is expected in March/April 2025 with sales to commence shortly thereafter. Preparations for US market launch are well advanced, with recently appointed experienced US-based executives, John Walker and Phillip Edmondson, driving the go-to-market strategy. Recruitment of the initial sales team, Key Opinion Leader engagements, distributor appointments and initiating medical education and advocacy programs to support early sales has commenced.

On the back of excellent sales traction, as evidenced by a third consecutive quarter of record revenue, the Company is now accelerating global commercialisation into five key jurisdictions in 2025 (Figure 1). The application for a Medical Device Licence from Health Canada is well advanced and is expected to be lodged shortly. The regulatory submission for Thailand is targeted for end of the March Quarter 25, the UK and EU regulatory submissions targeted for the September Quarter 25, followed by Brazil in the December Quarter 25. In addition to these planned submissions, the Company is investigating other ASEAN (eg Taiwan, Vietnam, Indonesia and Philippines) and Latin American markets.

The Company has a strong balance sheet with circa $33 million cash at bank and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets. Orthocell is targeting large addressable markets with ~1.8M peripheral nerve repairs estimated across existing (Australia, NZ and Singapore) and planned markets (USA, Canada, Thailand, EU/UK & Brazil). The combined global market opportunity for Remplir is estimated to be approximately US$3.2 billion (circa A$5 billion) with Orthocell targeting a 20% market share. Effective expansion into other markets would see an increase in these projections, demonstrating significant growth potential for the Company in the near term.

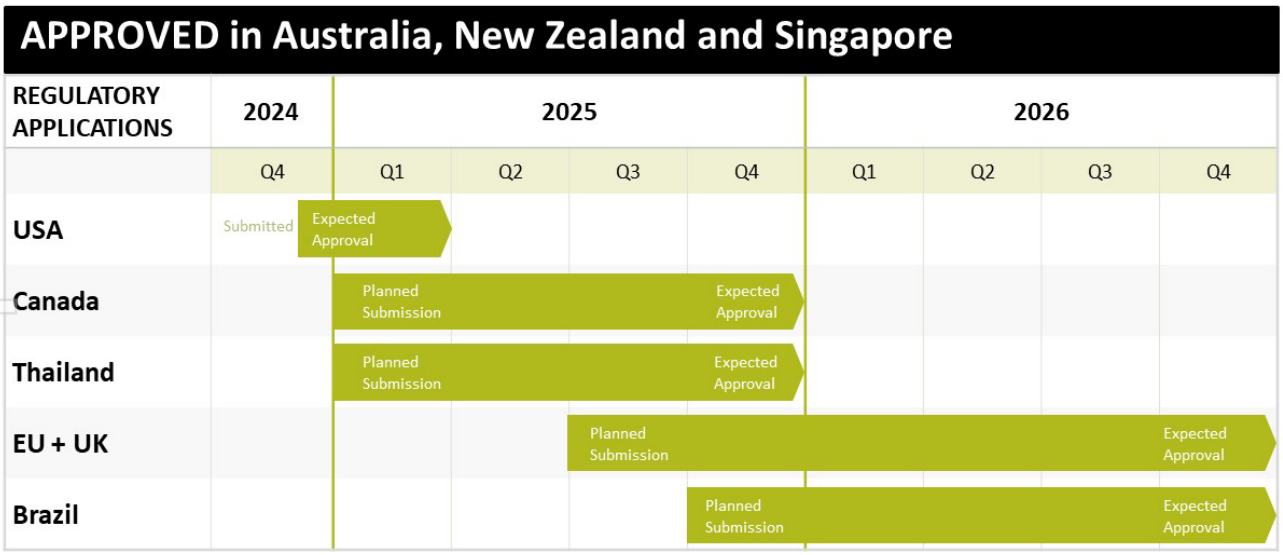

Figure 1: Global Regulatory Strategy for Remplir 2025-2026

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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) 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 **@Orthocelllltd** 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.