Orthocell Submits Canada Regulatory Application to Commence Sales of Remplir™ into US$75million Canadian market

- **Strong sales and record revenue in existing markets for Remplir™ are driving Orthocell to accelerate global expansion into multiple new markets in CY25 and rapidly enlarging the Company's revenue opportunity**
- **Orthocell has now submitted its regulatory application to Health Canada for approval to sell Remplir into the material US$75 million[1] Canadian market**
- **The Company expects Remplir to be approved in Canada in the second half of CY2025, with a further four key markets targeted for CY2025 including regulatory submissions planned for:**
  - **Thailand targeted for the March Quarter '25**
  - **UK and EU targeted for the September Quarter '25**
  - **Brazil targeted for the December Quarter '25**
- **Orthocell also remains on track to gain US FDA 510(k) regulatory clearance to commercially distribute Remplir into the critical US$1.6 billion[2] U.S. market, with approval expected in March / April 2025**
- **Accelerated global expansion will significantly increase the revenue opportunity for the Company, targeting a 20% share of the US$3.2 billion[3] of value in selected markets**
- **The Company has a strong balance sheet with circa $33 million[4] 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; 03 February 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has submitted an application to Health Canada (HC) for a Medical Device Licence (MDL) to sell its leading nerve repair product Remplir™ into the US$75 million[1] Canadian nerve repair market.

HC is the regulatory authority responsible for regulating the importation, manufacture, export, and supply of medical devices. Evaluation of Orthocell's application to HC is now in progress with clearance expected in the second half of calendar year (CY) 2025 quarter.

Remplir is a collagen wrap used in nerve repair surgery 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. Remplir has gained excellent sales traction since its Australian market launch in November 2022 and the Company has achieved three consecutive quarters of record revenue. There are ~180 orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries across Australia, New Zealand and Singapore.

Preparations for the US market launch are well underway ahead of market clearance from the FDA. Based on the statutory 90 calendar day review process for U.S. FDA 510(k) submissions, Orthocell anticipates market clearance for Remplir late March or early April 2025, with sales to commence shortly thereafter.

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

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

[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.

[4] Cash at 17th January, 2025

The US market represents a significant market opportunity for the Company, representing the largest and highest value nerve repair market estimated to be worth ~US$1.6 billion[2] U.S. per annum. The Company has appointed two experienced US-based executives to drive the go-to-market strategy, and Key Opinion Leader (KOL) engagements, distributor appointments and medical education programs to support early sales are also progressing.

As announced, the Company is also accelerating its plans to enter a number of other key markets across CY2025 including Thailand, United Kingdom, European Union and Brazil, with other ASEAN (e.g. Taiwan, Vietnam, Indonesia and Philippines) and Latin American markets also under evaluation. 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.

The Company has a strong balance sheet with circa AU$33 million[4] 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[3] (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 near-term growth potential for the Company.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

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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 CelGro™ 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, and is distributed globally by BioHorizons Implant Systems Inc. Striate+™ is cleared for use in the US(510k), Canada (MDL), Australia (ARTG), New Zealand (WAND), the UK (UKCA Mark) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies. 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.