Orthocell Receives $3.18m R&D Tax Incentive Refund

- **Orthocell receives a further boost to cash reserves with receipt of a $3.18 million refund from the Australian Government's Research and Development (R&D) Tax Incentive program**
- **The Company now holds circa $33 million[1] cash at bank and is very well funded to continue driving its global market commercialisation strategy**
- **Orthocell is on track to achieve US FDA clearance to commence sales of Remplir™ into the US$1.6 billion[2] U.S. market in late March or early April 2025**

Perth, Australia; 20 January 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has received a Research and Development (R&D) Tax Incentive refund of A$3,185,026 for the financial year 2023/2024.

Orthocell CEO and MD, Paul Anderson, said: *"We are in a very exciting phase at Orthocell. We hold a strong cash position of circa $33 million, are royalty free, have rapidly growing revenues, and are on track to achieve U.S. market clearance to start selling Remplir in the US$1.6 billion U.S. market in late March or early April 2025. With our experienced team, sales growth in existing markets showing clear traction and the significant potential for exponential revenue growth that the US market can deliver, we look forward to this next phase with great enthusiasm, and believe we are on track to become a key player in the US$4.5 billion[3] global medical device market."*

The R&D Tax Incentive is an Australian Government program to encourage innovation by supporting Australian companies to undertake R&D activities in Australia. Under the program, eligible companies can receive cash rebates of up to 48.5% for expenditure on R&D activities.

Release authorised by:
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About Orthocell Limited

[1] Cash at 17th January, 2025

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

[3] Nerve and Bone addressable markets include AUS, USA, EU/UK, SGP, BRZ, JAP, & THA. Referenced papers were used to estimate procedures per annum. Papers included both US and OUS databases and studies.

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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.