Orthocell submits Singapore Regulatory Application for Striate+™

- **Orthocell's global expansion strategy for its market leading guided bone and tissue repair product, Striate+™, continues to build with the submission of a regulatory application to the Health Services Authority of Singapore for approval to market and sell the Product**
- **Striate+ is gaining excellent traction and growing revenue in US, Europe, UK and Australia, supported by an outstanding 98.6% success rate from the Striate+ dental implant post-maketing clinical study**
- **Striate+ was recently approved in Canada, and is now pending approval for sale in Singapore and Brazil in the near term**
- **Orthocell is working with exclusive global distribution partner BioHorizons to achieve further regulatory approvals for Striate+ into multiple new large markets**
- **The Company has a strong balance sheet of $20.6 million, record revenue of $6.72m in FY24 (up 30% YoY) and is well-positioned to broaden its commercial footprint and grow product adoption and revenues in existing and new markets**

Perth, Australia; 29 July 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") today announced its application to market and sell its leading guided bone and tissue repair product Striate+™ in Singapore, has been accepted for review by Health Services Authority of Singapore (HSA). HSA is the Singaporean Ministry of Health's authority responsible for regulating the importation, manufacture, export, and supply of medical devices. Evaluation of Orthocell's application to HSA is now in progress.

Orthocell Managing Director, Paul Anderson, said: *"We are delighted to announce our regulatory application for Striate+ in Singapore, a key strategic stepping stone into the wider ASEAN market. Our global marketing program for Striate+ is really gaining traction, and this application is a testament to our team's continued efforts to make Striate+ available to patients and dental surgeons across the world. Once Singapore and Brazil applications are approved, Striate+ will be available for sale for use in guided bone and tissue repair in seven large and attractive markets."*

Striate+ is a collagen membrane used to support guided bone regeneration in dental implant procedures. Striate+ is approved for use in the US, Australia, New Zealand, Europe, UK and Canada and is exclusively distributed by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies.

Striate+'s high quality performance since launch is underpinning BioHorizon's pursuit of other large, attractive markets where they have established accounts and/or distribution networks. Orthocell is working with BioHorizons to accelerate further development of the regulatory strategy to expand access into other regions.

The strategic partnership has resulted in significant revenue growth for Orthocell, with increasing quarterly revenue and record annual total revenue in FY24 of $6.72 million, up 30.4% from the previous year (FY23) of $5.15 million. This revenue growth is evidence that Orthocell's products are achieving strong uptake in their respective markets.

Orthocell is well positioned to drive Striate+ into global markets, with a strong cash position of $20.6m[i], focussed regulatory program targeting multiple strategic markets and a global distribution partner driving product marketing and sales.

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 Collagen Medical Device platform 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, Canada, Australia , New Zealand, UK and Europe 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 and New Zealand markets. 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.

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[i] Cash position as at 30 June, 2024