Orthocell Receives Regulatory Approval to Commence Sales of Striate+™ in Canada

- **Orthocell has received a Medical Device Licence from Health Canada, allowing the Company to commence sales of its market leading dental guided bone regeneration product, Striate+™, in the key market of Canada.**
- **Canadian regulatory approval complements existing approvals in the US, Europe/UK, Australia and New Zealand, where the Company has fast growing sales and has just recorded record revenue for FY24.**
- **Orthocell's distribution partner for Striate+™, Bio Horizons, is already well established in the Canadian market which will facilitate a fast transition to first sales and revenue generation from this region.**
- **The Canadian market alone is estimated to be worth A$60 million, with the global market opportunity for these products estimated to be in excess of A$1 billion[1].**
- **Striate+ is gaining strong sales traction in its existing markets, supported by an outstanding 98.6% success rate from the Striate+ dental implant post-market clinical study.**
- **Given traction in existing markets, Orthocell is working with BioHorizons to accelerate approvals in a number of other key global markets.**
- **The Company has a strong balance sheet of $20.6 million in cash to support its growth strategy.**

Perth, Australia; 11th July 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce Heath Canada has granted a Medical Device Licence (MDL) for the Company's market leading product, Striate+™, for use in guided bone regeneration in dental implant procedures. Approval in Canada paves the way for the commencement of sales in another key region for the Company.

Orthocell Managing Director, Paul Anderson, said: *"Canadian approval for Striate+™ is further validation of Orthocell's expanding global footprint. Approval in this market complements our FDA approval and strengthens the Company's position to increase revenue, in collaboration with our valued partner BioHorizons. Additionally, it reaffirms the high quality of our product and world-class, scalable manufacturing process."*

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 and the UK and is distributed globally by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies.

Striate+'s high quality performance since launch is underpinning BioHorizons 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 for Striate+ to expand access into other regions as soon as possible.

This strategic partnership has resulted in significant revenue growth for Orthocell, with increasing quarterly revenue growth of an average 9%, compounded for the last seven quarters. Orthocell has recently announced

[1] Source: Grand View Research, Dental Implants Market Size, Share and Growth Report , 2030

it has achieved record annual total revenue in FY24 for a total of $6.72m. This revenue growth is evidence that Orthocell's products are achieving strong uptake in their respective markets.

Orthocell is well funded for its global market expansion, with a strong balance sheet and $20.6 million in cash to support its growth strategy.

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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), New Zealand (WAND), UK (UKCA Mark) 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 **@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.