Orthocell Receives Regulatory Approval for Striate+ in Brazil:
Marks First Market Authorization in Latin America

- **Orthocell has received regulatory approval from the Brazilian Health Regulatory Agency (Agencia Nacional de Vigilancia Sanitaria or 'ANVISA'), allowing the Company to commence sales of its market-leading dental guided bone regeneration product, Striate+™, in the large and important market of Brazil**
- **Brazil is a US$65 million[1] market opportunity and a key part of the wider US$735 million[2] global market the Company is targeting for Striate+ in select jurisdictions**
- **Orthocell is working with its exclusive global distribution partner BioHorizons on an initial market launch and expects to commence commercial distribution of Striate+ in Q4 CY 2025**
- **Regulatory approval in Brazil adds to the growing list of approved markets for Striate+, which includes the US, Europe, UK, Australia, New Zealand, Canada and Singapore**
- **Brazil has a key strategic role in future expansion into Latin American countries, with approvals from ANVISA highly regarded by other regulatory authorities in the region**
- **Striate+ is gaining robust sales growth, driven by positive feedback from dental surgeons and backed by an impressive 98.6% success rate from the Striate+ dental implant post-market clinical study**
- **The Brazilian approval for Striate+ closely follows the Company's pivotal US FDA clearance for nerve repair device Remplir last week, which demonstrates that execution of the Company's global commercialisation push across both Striate+ and Remplir is on track**
- **The Company has a strong balance sheet with circa ~$32 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; 09 April 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce that Brazilian Health Regulatory Agency, ANVISA, has granted regulatory approval for the Company's market-leading dental membrane, Striate+™, for use in guided bone and tissue regeneration applications. Approval in Brazil adds to existing approvals in the US, Europe, UK, Australia, New Zealand, Canada and Singapore, and will further support the robust sales growth achieved in these existing markets. Orthocell is working with BioHorizons, the global marketing and distribution partner for Striate+, on an initial launch into the US$65 million Brazilian dental membrane market and expects to commence commercial distribution of Striate+ in Q4 CY 2025.

Orthocell CEO and MD, Paul Anderson, said: "We are delighted to receive regulatory approval for Striate+ in Brazil. This approval provides additional validation of Orthocell's high-quality products, manufacturing processes and quality systems. Moreover, it enhances our ability to drive revenue growth as our distribution partner expands into global markets. Importantly, we remain well capitalised to roll out our expansion plans for our collagen regenerative membranes Striate+ and Remplir in eight jurisdictions throughout the world. We have ample manufacturing capacity at our Perth facility to deliver both products into these markets."

[1] Brazil dental membrane market size was estimated using referenced papers from both US and OUS databases and studies

[2] Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

[3] Cash at bank as at 26th March, 2025

Striate+ is a resorbable collagen membrane for use in dental bone and tissue regeneration applications, including dental implant procedures. Striate+ is designed to protect the bone defect from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and reliable formation of high-quality bone.

Striate+ is experiencing strong sales growth in existing markets, fuelled by overwhelmingly positive feedback from dental surgeons. The product's unique features—such as its ease of use, ability to conform to treatment surfaces, and promotion of more efficient bone growth—have driven high adoption and contributed significantly to its success.

Striate+'s approval in Brazil and its high-quality performance is driving BioHorizons' pursuit of other large, attractive Latin American markets where they have established accounts and/or distribution networks. In particular, a regulatory application for Striate+ in Colombia is anticipated within the next 3 months, with further regulatory applications under review.

The Company has a strong balance sheet with circa AU$32 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. The combined global market opportunity for Striate+ is estimated to be approximately US$735 million 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.

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ortho·cell
advancing tissue repair & regeneration

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, is approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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.