For personal use only

Orthocell Receives Major International Regulatory Approval for Striate+ in the Key Market of Singapore

- **Orthocell has received regulatory approval from Singapore's Health Sciences Authority (HSA), allowing the Company to commence sales of its market leading dental guided bone regeneration product, Striate™, in the key market of Singapore**
- **Singapore regulatory approval complements existing approvals for Striate+ in the US, Europe/UK, Australia, New Zealand and Canada**
- **Singapore is a key regulatory hub, recognised both as a leading destination for advanced medical treatments in the region, and serves as a gateway to other major ASEAN markets**
- **Orthocell's global marketing and distribution partner for Striate+, BioHorizons, is already established in the Singaporean market which will facilitate a fast transition to first sales and revenue generation from this region**
- **Striate+ is gaining robust sales growth in a major global market opportunity valued at over AU$1 billion[1] in selected addressable markets. This momentum has been driven by positive feedback from dental surgeons, backed by an impressive 98.6% success rate from the Striate+ dental implant post-market clinical study**
- **Building on success in existing markets, the Company is working with BioHorizons to fast track its expansion into several other large new markets, including Brazil, with approval expected in the next 3-6 months**
- **The Company has a strong balance sheet with circa $33 million[2] 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; 18 March 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce that Singapore's Health Sciences Authority (HSA) has granted regulatory approval for the Company's market leading dental membrane, Striate+™, for use in guided bone and tissue regeneration applications. Approval in Singapore complements existing clearances in the US, Europe/UK, Australia, New Zealand and Canada and will further support the robust sales growth being delivered from existing markets. Orthocell's global marketing and distribution partner for Striate+, BioHorizons, is already well established in the Singaporean market which will facilitate a fast transition to first sales and revenue generation from this region.

Orthocell CEO and MD, Paul Anderson, said: "We are delighted to receive Singaporean regulatory approval for Striate+ in this important regional gateway market. 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."

Striate+ is a sterile, 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

[1] 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.

[2] Cash at 17th January, 2025.

For personal use only

tissue, to provide a favourable environment for osteogenesis and to assure 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.

Singapore is a strategic regulatory market and can be used as a stepping stone to approvals in other ASEAN markets. Singapore is known for its efficiency, high standards and state of the art medical facilities, and is an important destination for medical treatments and tourism in the region.

Orthocell's global regulatory strategy for Striate+ continues to progress, with the Company on track to receive regulatory clearance in Brazil in 3-6 months.

The Company has a strong balance sheet with circa AU$33 million[2] 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 AU$1 billion[1] 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:
Paul Anderson
Orthocell Ltd CEO and MD

For more information, please contact:

General & Investor enquiries

Paul Anderson
Orthocell Limited
CEO and MD
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

About Orthocell Limited
ACN 118 897 135
Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

For personal use only

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.