

Orthocell Receives First Major International Regulatory Approval for Remplir in the Key Market of Singapore

- Orthocell has received regulatory approval from the Health Sciences Authority (HSA) in Singapore, allowing the Company to commence sales of its market leading nerve repair product, Remplir™
- This landmark regulatory approval in Singapore marks the first major international approval of Remplir outside the existing markets of Australia and New Zealand
- Singapore is a strategic regulatory jurisdiction, both as a destination for sophisticated medical treatments in the region and as a regulatory gateway to other substantial ASEAN markets
- Orthocell is in advanced discussions with an experienced international medical device distributor ahead of the Singapore market launch anticipated for Q1 CY25
- The global market opportunity for Remplir is estimated to exceed US\$3.5 billion¹
- The Company continues to accelerate its regulatory program for other jurisdictions, including the key US market, estimated to be worth in excess of \$1.6 billion², along with Canada, UK, Europe and other ASEAN markets
- Orthocell is on track to receive US FDA regulatory clearance in Q1 CY25
- Remplir is gaining significant traction with new and existing surgeons in Australia and New Zealand with record quarterly revenue reported for the September 24 Quarter.

Perth, Australia; 8 October 2024: 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 product, Remplir™, for use in peripheral nerve repair. Approval in Singapore is the first major international regulatory approval for Remplir outside of Australian and New Zealand where the product is currently sold. Commencement of sales early next year in another key region for the Company will further compliment the excellent revenue growth being delivered in these existing markets. Orthocell is in advanced discussions with an experienced international distributor ahead of the market launch, which will fast track first sales in the region.

Orthocell CEO and MD, Paul Anderson, said: “We are delighted to receive Singaporean regulatory approval for Remplir in this important regional gateway market. This approval is further validation of Orthocell’s, high-quality product, manufacturing processes and expanding global footprint. This approval strengthens our position to increase revenue and builds further confidence in our US FDA clearance anticipated in Q1 2025.”

“We are completely focused on growing revenue in our existing markets, as well as adding new jurisdictions, because we have absolute confidence in Remplir as a best-in-class product. We are seeing surgeons achieve consistent and predictable outcomes using Remplir, which is translating to growing revenues.”

Remplir is a collagen wrap to augment nerve repair surgery. Remplir is approved for sale in Australia and New Zealand and distributed by Device Technologies (DVT), a respected name in the provision of medical devices

¹ Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

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



and healthcare solutions across Australia, New Zealand and Asia. Orthocell has been working with DVT to introduce Remplir, with 130+ orthopaedic and plastic surgeons across Australia and New Zealand now using Remplir in peripheral nerve repair surgeries.

The feedback from surgeons has been extremely encouraging and product adoption has been strong, driven by Remplir's unique qualities that enable the reduction of damaging sutures, creation of an optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period.

Singapore is a strategic regulatory market and can be used as a stepping stone to approvals in other ASEAN markets (e.g. Thailand, Malaysia, Vietnam, Indonesia and Philippines). Singapore is known for its efficiency, high standards and state of the art medical facilities, and as such is an important destination for medical treatment in the region.

Orthocell's global regulatory strategy for Remplir continues to progress, with the Company on track to receive regulatory clearance from the US FDA in 1Q CY25 and applications are planned for Canada, Thailand and EU and UK within the next 6-12 months.

Orthocell is targeting a large addressable **nerve repair market estimated to be worth in excess of US\$3.5 billion¹**, with ~2.0M peripheral nerve repairs estimated to be performed across existing Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan and Thailand.

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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 its 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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