ASX Announcement

Orthocell Submits Regulatory Application for Commercial Distribution of Remplir™ into the US$750 million EU + UK Nerve Repair Market

Regulatory approval expected in 3Q CY26

- Orthocell has submitted its application to the British Standards Institution (BSI) seeking approval to commercially distribute Remplir™ into the US$750 million[1] EU and UK nerve repair market, comprising an estimated 500,000 surgical repairs of peripheral nerves per year.
- Regulatory approval expected to be received in 3Q CY26.
- Orthocell requires certifications, known as "CE" and "UKCA", from approved EU and UK assessor BSI, in order to commence distribution of Remplir in the EU and UK markets.
- The submission is supported by compelling Real-World Evidence (RWE) from the recent Remplir post-market clinical follow-up study demonstrating an overall treatment success rate of 81.1% across nerve repair procedures. This milestone provides robust clinical evidence and forms a critical component of the technical documentation required for EU and UK Medical Device Regulation (MDR) certification.
- Implementation of a go-to-market strategy utilising in-country specialist distributors and appointment of a Key Opinion Leader panel of surgeons is under way.
- The EU and UK submission is a key milestone in Orthocell's global expansion strategy for Remplir, targeting a Total Addressable Market in selected jurisdictions in excess of US$3.5 billion[2].
- Remplir is already approved and selling in Australia, New Zealand, Singapore, the US and Hong Kong, with first sales expected in Canada and Thailand in the near term.
- Orthocell remains well funded, with approximately $50 million in cash, providing a strong balance sheet to support its global distribution strategy, progress its EU and UK regulatory programs, and drive the ongoing commercial rollout of Remplir in existing and new markets.

Perth, Australia; 15 December 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has submitted a regulatory application for approval to commercially distribute its nerve repair product, Remplir™, into the EU and UK markets.

[1] EU and UK nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies.

[2] Nerve repair market size was estimated using referenced papers from both US and OUS databases and studies

These markets represent a Total Addressable Market (TAM) of US$750 million with approximately 500,000 peripheral nerve repair procedures undertaken annually.

Orthocell has submitted its regulatory application for Remplir for evaluation by the approved EU and UK notified body, British Standards Institution (BSI). The Company expects to receive the required "CE" (European Conformity) and "UKCA" (UK Conformity Assessed) certification, allowing commercial distribution of Remplir, in 3Q CY26.

The EU and UK submission is underpinned by interim data from Orthocell's ongoing multi-centre Remplir real world evidence (RWE) post-market clinical follow up (PMCF) study. The study demonstrated an overall treatment success rate of 81.1% across procedure types, with 81.2% of innervated muscles achieving functional motor recovery and 89.5% of nerve decompression procedures resulting in significant improvement or complete symptom relief. Importantly, no post treatment complications or adverse reactions to Remplir were reported in any patient, with outcomes consistent with previously published clinical trial data. Further details are included in the Company's ASX announcement dated 8 September 2025.

Orthocell is confident that the study results and established PMCF framework will continue to meet the ongoing clinical data generation requirements under the EU and UK MDR. Combined with existing clinical data and growing surgeon adoption, the results position Remplir to play a central role in redefining nerve repair surgery and improving functional outcomes for patients with traumatic and chronic nerve injuries.

Orthocell's go-to-market strategy will involve independent in-country distributors and the process of sourcing and assessing distributors is underway in conjunction with a local expert consultant. The Company has also commenced the process of forming a Key Opinion Leader panel of surgeons with a view to targeting specific strategically important hospitals once regulatory clearance is obtained.

Orthocell CEO and MD, Paul Anderson said "We are thrilled to submit our EU and UK regulatory application for Remplir, marking an important milestone in our global expansion strategy. The application is underpinned by the compelling 81.1% treatment success rate from our recent Real World Evidence study, together with previously published clinical data and rapidly increasing surgeon use.

We expect to receive clearance from the BSI in the second half of 2026 and in the interim, we'll be focused on advancing our go-to-market strategy to be prepared to generate sales as soon as possible thereafter. The EU and UK has the potential to be our second largest market after the US and is therefore a pivotal component of our global expansion strategy."

The application advances Orthocell's global expansion strategy with Remplir already approved and selling in Australia, New Zealand, Singapore, the US and Hong Kong, and first sales expected in Canada and Thailand in the near term.

Orthocell ultimately targets a TAM in selected jurisdictions of more than US$3.5 billion. The Company remains focused on driving rapid market adoption of Remplir supported by a strong balance sheet (circa A$50 million in cash and no debt) and ongoing investment in clinical evidence and medical education initiatives.

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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 the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed a network of specialist US distributors and recorded initial sales. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore where it is distributed by Device Technologies Group. Other Remplir approvals include Thailand, Canada and Hong Kong. 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.