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ASX Announcement

Orthocell's Strategic Partner Marine Biomedical Receives U.S. FDA Clearance for PearlBone™

FDA 510(k) clearance unlocks the U.S. market for innovative marine-derived bone regeneration technology, strengthening Orthocell's biologically driven product portfolio

- **Marine Biomedical has received U.S. FDA 510(k) clearance for PearlBone™**, its innovative marine-derived bone graft substitute developed from sustainably sourced pearl shell.
- **FDA clearance enables PearlBone to be marketed in the United States** for its cleared indications, representing a significant milestone in the product's commercialisation pathway.
- **Orthocell holds an 12% equity interest in Marine Biomedical**, following its A$1.05 million strategic investment, and has secured a first right of refusal over global distribution rights for PearlBone and future bone repair and regeneration products.
- **PearlBone provides Orthocell with an opportunity to expand its biologically driven product portfolio** into the substantial global bone repair and regeneration market, complementing its established nerve and tendon repair technologies.
- **Marine Biomedical is progressing commercial readiness activities ahead of the planned introduction of PearlBone into the U.S. market**.

Perth, Australia; 03 November 2026: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to announce that its strategic partner, Marine Biomedical Pty Ltd (Marine Biomedical), has received U.S. Food and Drug Administration (FDA) 510(k) clearance for PearlBone™, its innovative marine-derived bone graft substitute.

The FDA clearance represents a significant regulatory milestone for Marine Biomedical, enabling PearlBone to be marketed in the United States for its cleared indications and advancing the product towards commercialisation in one of the world's largest medical device markets.

PearlBone is a next-generation bone substitute developed using sustainably sourced pearl shell from Western Australia's Kimberley region. The innovative biomaterial harnesses the natural properties of nacre, the biomineralised structure of pearl shell, to support bone repair and regeneration. The product has potential applications across orthopaedic, trauma and reconstructive surgery.

Strategic value for Orthocell

Orthocell's investment in Marine Biomedical reflects the Company's strategy to broaden its portfolio of biologically driven regenerative medicine products across bone, nerve and tendon repair.

In January 2026, Orthocell finalised a strategic investment in Marine Biomedical, increasing its equity interest to 12% for a total investment of A$1.05 million. The agreement also secured Orthocell a first right of refusal over global distribution rights for PearlBone and future bone repair and regeneration products.

FDA clearance is an important step in de-risking the regulatory pathway and advancing the commercial opportunity for PearlBone. It also creates the potential for Orthocell to leverage its established U.S. surgeon relationships, distributor network and commercial infrastructure to support the product's introduction to market, subject to the exercise of its contractual rights and agreement of definitive commercial arrangements.

Orthocell believes PearlBone has the potential to complement its existing portfolio, providing surgeons with an expanded suite of biologically advanced solutions for complex tissue repair and reconstruction.

Advancing commercialisation

Marine Biomedical is progressing commercial readiness activities in preparation for the U.S. launch of PearlBone, including manufacturing readiness, market development and engagement with potential commercial and clinical partners.

The FDA clearance follows years of scientific development, preclinical evaluation, manufacturing validation and regulatory preparation. PearlBone is manufactured at Marine Biomedical's purpose-built facility in Broome, Western Australia, supporting the development of advanced biomedical manufacturing capability in regional Australia.

Orthocell Chair, John Van Der Wielen, said: *"FDA clearance for PearlBone is an exciting milestone for Marine Biomedical and an important development for Orthocell.*

"Our investment in Marine Biomedical was made with a clear strategic objective: to secure exposure to an innovative bone regeneration technology with the potential to complement Orthocell's established nerve and tendon repair portfolio.

"Achieving FDA clearance is a significant step towards unlocking that opportunity. We believe PearlBone has considerable potential in the global bone repair and regeneration market, and we look forward to working with Marine Biomedical as it progresses towards commercialisation."

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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.

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