



ASX Announcement

ortho·cell

U.S. SECTION 232 TARIFFS NOT EXPECTED TO APPLY TO REMPLIR™

Perth, Australia, 8 April 2026: Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) notes the announcement by the United States Administration on 2 April 2026 regarding its intention to impose tariffs on certain pharmaceutical products imported into the United States under Section 232 of the Trade Expansion Act.

Following an initial review, Orthocell is confident that, as a medical device, its flagship product Remplir™ is not expected to be subject to the proposed pharmaceutical tariffs.

This distinction reinforces Orthocell’s strategic positioning within the U.S. market and supports continued momentum in the Company’s commercial rollout of Remplir.

Orthocell has already established a strong operational foothold in the United States, with approximately 4,000 units of Remplir currently in-market, none of which are impacted by the proposed tariff measures.

The proposed measures are focused on pharmaceutical pricing frameworks. As a medical device, Remplir sits outside these frameworks, positioning Orthocell outside the scope of these policy settings.

The Company believes these factors position Orthocell favourably relative to pharmaceutical-based products and enable it to continue executing on its U.S. growth strategy without disruption or financial impact.

Orthocell will continue to monitor developments and will update the market as required.

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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 14 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 and Canada. 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.