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Striate+™ US market entry update

- **US Key opinion leader sales growth milestone of 1,500 Striate+™ units achieved**
- **Approvals received to upgrade existing facility** and scale up Striate+™ manufacturing capacity to >100,000 units per year
- **Commissioning of upgraded facility expected Q4 CY2022**
- **Distributor discussions progressed** and the Company is in advanced discussions to engage its first US distributor and establish Striate+™ as the premium dental membrane

Perth, Australia; 28 February 2022: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce a US market entry update for the Striate+™ premium dental membrane, with the achievement of a significant US key opinion leader (KOL) sales growth milestone and approvals to upgrade Orthocell's existing facility and scale up Striate+™ manufacturing capacity to >100,000 units per year.

Following on from the FDA 510(k) clearance to supply Striate+™ for dental bone and tissue regeneration procedures in the US, the Company has been executing a strategy to engage a US distribution partner. The strategy involves establishing a high-quality logistics solution, developing a KOL network and implementing a KOL-led education and product awareness program (clinician advocacy program).

The Company's clinician advocacy program has progressed significantly, with eighteen highly respected KOL's across the EU, UK, US and AUS, who are actively representing the Company as product ambassadors and using Striate+™ in their dental surgeries. Product sales of Striate+™ from the US KOL's alone has reached over 1,500 units. These industry-leading clinicians continue to assist the Company in growing product awareness, expanding the network of key accounts and supporting ongoing discussions with potential distribution partners.

Orthocell has been actively preparing to scale up its manufacturing capacity of Striate+™. The Company has approval to commence construction of a new clean room, increasing the manufacturing capacity to >100,000 Striate+™ units per annum. The cleanroom, equipment and operator costs are fully funded, and construction is scheduled to commence in Q1 CY2022. Commissioning of the manufacturing facility is expected in Q4 CY2022.

Orthocell Managing Director, Paul Anderson, said: "Orthocell has made significant progress towards US market entry, forming a strong clinical network validating Striate+™ as a premium dental membrane. We are now well-positioned to secure a US distributor and I look forward to what is shaping up to be a very exciting year ahead for the Company."

Release authorised by Paul Anderson
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About Orthocell Limited

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™, a collagen medical device which facilitates tissue repair and healing in a variety of dental and orthopaedic reconstructive applications. Orthocell recently received FDA 510(k) approval for Striate+™, the first application of the CelGro™ platform for dental GBR applications. Striate+ is also approved in Australia (ARTG) and Europe (CE Mark) for the same use. Remplir™ and SmrtGraft™ are under evaluation and only available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are the cell therapies (OrthoATI™) and Autologous Chondrocyte Implantation (OrthoACI™), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is accelerating the development of OrthoATI™ in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit www.orthocell.com.au 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.