Striate+™ re-certified under new European medical device regulations

- Striate+™, used for dental bone and tissue regeneration procedures, has received regulatory approval under the new European Medical Device Regulations (MDR)
- Striate+ originally gained EU regulatory approval in 2017, but was required to be re-certified under MDR to be legally sold in the 30 European Economic Area member countries
- Re-certification under MDR allows continued sales of Striate+ in all 30 European Economic Area member countries
- Re-certification follows the first anniversary since executing a global Striate+ exclusive licence and distribution agreement with BioHorizons
- In partnership with BioHorizons, Orthocell is now well-positioned to gain rapid product uptake and commercial traction in US, AU and EU, as well as expanding into other global healthcare markets

Perth, Australia; 24 August 2023: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce that Striate+™ has been certified under the new European Medical Device Regulations (MDR). Striate+ was originally approved in 2017 (as CelGro™) for dental bone and tissue regeneration procedures under the Medical Device Directives (MDD), however, from May 2021, all approved medical devices in Europe were required to be re-certified under MDR to be legally sold in the EU. Re-certification under MDR allows the continued sale of Striate+ in all 30 European Economic Area member countries.

Orthocell Managing Director, Paul Anderson, said: *"Re-certification to the MDR is a significant milestone for the Company as it confirms Striate+, manufactured by the Company in Western Australia, complies with the more stringent safety and efficacy standards now in place in the EU. Additionally, it enables BioHorizons, our marketing and distribution partner, to continue to execute their plans to enter the EU market without restriction. We look forward to working with BioHorizons to launch Striate+ in the EU and expand into multiple EU countries."*

The Company achieved EU certification (CE Mark) for Striate+ in 2017 (as CelGro™) for use in dental bone and tissue regeneration procedures under the Medical Device Directives (MDD). A new legal framework, the Medical Device Regulations (MDR), became applicable to medical devices sold in the EU from May 2021. Medical devices that received CE mark under the MDD are required to be re-certified under the MDR to continue to be sold in EU member countries and the United Kingdom.[1]

The MDR expanded on the requirements of the MDD to enforce improvements to the safety and performance of medical devices in Europe. Application of the MDR was intended to ensure a higher level of protection for patients and users of medical devices, with increased scrutiny on device safety throughout the full product lifecycle (design, testing, manufacturing, commercialisation, and long-term use). The MDR places much stricter requirements on the quantity and quality of clinical data and more stringent post-market monitoring. Therefore, the benchmark for medical devices looking to gain marketing approval in the EU is significantly higher under MDR than under MDD.

BioHorizons Update - Growing sales and expanding into new markets

Re-certification under the MDR follows the first anniversary of the Striate+ global exclusive license, manufacturing and distribution agreement with BioHorizons. In consideration of the license granted, Orthocell

[1] Under post-Brexit agreements, CE-marked devices compliant with the MDR can continue to be sold in the UK until June 2030. After this time, devices must be certified under the UK Medical Device Regulations to be placed on the UK market.

received in cash AU$21,461,686 million[2] (USD $14,774,225 million), net of fees. BioHorizons is part of Henry Schein, Inc. (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regeneration products for dentists and dental specialists. The Company has a broad product offering, including dental implants, guided surgery, digital restorations and tissue regeneration solutions for the replacement of missing teeth. BioHorizons products are available in 90 markets around the world. For more information, visit biohorizons.com.

Following BioHorizons' launch of Striate+ into the US market in November 2022, the Company reported that sales unit volumes for FY23 were ahead of expectations with the outlook in FY24 looking even stronger. Since signing the distribution agreement with BioHorizons, Orthocell has supplied more Striate+ units than the initial budgeted guidance, and is on track to launch Striate+ in the EU in 3Q CY2023. Orthocell is leveraging existing regulatory approvals and working with BioHorizons to gain entry into other international markets including Canada, Brazil and Japan.

The partnership with BioHorizons, its established relationships with surgeons and successful track record in driving the market entry of high-quality products, now positions Orthocell to gain rapid product uptake and commercial traction in the US, AU and EU, as well as expanding into other global healthcare markets.

Market opportunity for Striate+™

Striate+ is a market leading resorbable barrier membrane used in dental guided bone and tissue regeneration procedures. Market sizing undertaken by Orthocell suggests that Striate+ could be applicable to >5m procedures per year, which equates to a retail market opportunity of approximately >US$720m[3]. Increasing prevalence of oral disorders, ageing population and advances in tooth restoration technology have driven the growth in the dental implant market, increasing the demand for premium dental barrier membranes.

Clinical studies have shown Striate+ supported transition from two-stage to single-stage dental procedures, reducing the procedure time by several months[4]. This is of significant interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures. Its uptake is expected to be driven by surgeons' preference for high quality, easy to use devices facilitating better patient outcomes. Striate+ is approved for use in EU, UK, AU and US.

Release authorised by Paul Anderson
Managing Director
Orthocell Ltd.

[2] After transaction costs and assuming 1 United State Dollar is equal to 1.45 Australian Dollars
[3] Internal Orthocell modelling based on iData Research Inc. Dental Barrier Membrane Market, US, 2022.
[4] Data on file

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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 CelGro™ 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) 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, 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 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.