Outstanding 98.6% success rate from Striate+™ dental implant post-market clinical study

- **Post-market clinical study results displayed that dental implant treatment with guided bone regeneration utilising Orthocell's Striate+™ dental membrane resulted in an outstanding 98.6% success rate.**
- **This compelling real-world evidence confirms Othocell's dental membrane product, Striate+, as the optimal medical device for all types of guided bone regeneration and dental implant procedures.**
- **These results will raise the profile of Striate+ with new and existing dental surgeons and greatly assist the Company's exclusive global distributor, BioHorizons, in growing product adoption.**
- **The addressable market for the Striate+ product is estimated to be worth more than US$700 million per annum[1] in which Orthocell is already growing its revenue.**

Perth, Australia; 14 May 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce results from the Striate+™ dental implant post market clinical study, ("Striate+ Study", "the Study"). The Study showed that dental implant procedures using Orthocell's Striate+ dental membrane for Guided Bone Regeneration ("GBR"), resulted in a 98.6% implant success rate.

The Striate+ Study followed on from the Post-Market Clinical Follow-up (PMCF) study, a key component of the clinical data package for re-certification of EU market approval under the new European Medical Device Regulations (MDR). The Striate+ Study aimed to further investigate the effect of the Striate+ collagen membrane on patient-related systemic factors, as well as implant and procedure related factors of peri-implant Marginal Bone Level (MBL) following GBR and implant placement. The result displayed that a desirable level of bone formation and stability was achieved in all areas, demonstrated by the high rate of treatment success.

Study results have been submitted for presentation at the upcoming European Association for Osseintegration ("EAO") annual meeting on the 24-26 October 2024. The results follow a successful collaboration between Professor Giuseppe Luongo at the Department of Neuroscience and Reproductive and Odontostomatological Science, University of Naples Federico II, Naples, Italy and Professor Minghao Zheng at the UWA Medical School, University of Western Australia.

Chief investigator and dental surgeon, Professor Giuseppe Luongo, said: *"Striate+ is a best-in-class dental membrane that facilitates the highest quality bone and tissue repair. Predictable and high-quality bone regeneration is of utmost importance to deliver functional and aesthetically pleasing outcomes for patients. We are delighted to share this compelling real-world data."*

Guided bone regeneration and dental implant procedures

Dental implants are an effective and rapidly growing area of orthodontic treatment. Often patients lack sufficient bone volume to adequately secure the dental implant and, as a result, require GBR as part of the dental implant procedure. GBR is a highly successful approach for restoring dental bone defects alongside

[1] Addressable market estimate was developed by the Company using reports from US healthcare databases and referenced papers of studies conducted both within and outside the US.

implant placements, with success rates often higher than 70%.[2] However, treatment success can be affected by a variety of patient factors, such as smoking, other medical conditions, or peri-implantitis, all of which can affect the amount of bone regeneration needed to stabilise the dental implants.

Study objectives

The study aimed to determine the effect of Striate+ collagen membrane on patient-related systemic factors, as well as implant-related and procedure-related factors of peri-implant MBL following GBR and implant placement. Data were obtained from 99 patients receiving at least one dental implant and GBR procedure using Striate+ dental membrane between July 2018 and December 2023. Patients in the study varied in age, gender, smoking status, medical history, implant brand, implant size, surgical procedure and void filling materials used. The MBL was recorded using radiographic data at implant placement, re-entry surgery and follow-up visits. Influencing factors of ΔMBL between visits were further analyzed.

Study results

A total of 143 implants, placed in 99 patients (44 [44.4%] men and 55 [55.6%] women), were included in the study analysis. The mean age was 64.04 ± 11.76, ranging from 23 to 84 years old. The median follow-up period was 21 weeks, ranging from 6 to 230 weeks. Mean MBL values at implant placement, re-entry surgery and last follow-up visit were 0.56 ± 0.66, 0.80 ± 0.69, and 0.94 ± 0.75, respectively. Of the 143 implants, 127 (88.8%) implants have simultaneous GBR and implant placement. One hundred and twenty-six (88.1%) implants have MBL values within the normal physiological limits, while only 2 (1.4%) failed due to peri-implantitis, **resulting in an implant success rate of 98.6%**. No contributing factors associated with ΔMBL were identified by multivariate regression analysis in this study.

The Striate+™ Advantage

Striate+ is manufactured by Orthocell at its quality-controlled facility in WA and distributed globally by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies. BioHorizons completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader (KOL) accounts and other major customers. The ramp up of product sold in the ~18 months since market launch is gaining traction with the product now sold in the US, EU & UK and AUS. The Striate+ Study will likely raise the profile of Striate+ with existing and new dental surgeons and assist BioHorizons in growing product adoption in an addressable market estimated to be worth more than US$700 million per annum.

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[2] Orthocell systematic literature review 2023. Data on file

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 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.