

## CelGro® gains Australian reimbursement

- CelGro® Dental granted inclusion on the Australian Prostheses List
- The Prostheses List defines the minimum value of benefit private insurers pay for CelGro®

  Dental used in approved dental bone and soft tissue repair procedures
- Positions Orthocell favorably on its pathway to secure distribution partners

**Perth, Australia; 03 March 2021:** Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has received notification from the Australian Government Department of Health that CelGro® Dental has been included on the Australian Prostheses List. Inclusion on the PL enables dental practitioners to receive reimbursement from private insurers for use of CelGro® Dental in approved dental bone and soft tissue repair procedures, reducing costs to the patient.

**Orthocell Managing Director Paul Anderson, said:** "Inclusion of CelGro® Dental on the Prostheses List is the culmination of translational research and a regulatory program to bring this product to the Australian market. I am delighted that patients now have access to a premium dental membrane product designed, manufactured and reimbursed in Australia."

Receiving approval to be included on the Prostheses List follows the recent US and Australian market approvals for CelGro® collagen medical device, for introduction into the global dental bone and tissue regeneration markets, estimated at US\$1 billion per annum¹. Inclusion on the PL has been received ahead of the Company's previously reported expectations.

Based on surgeon feedback and clinical data, CelGro® Dental (recently renamed Striate+<sup>TM</sup>) has distinct advantages over other similar products and may assist surgeons to deliver improved patient outcomes through superior handling characteristics, tissue integration qualities and improved bone healing.

This reimbursement will assist the Company in pursuing negotiations with multi-national dental companies and national dealers for marketing and distribution rights, with Orthocell to retain manufacturing of the finished product. With US, EU and Australian market approval achieved and key opinion leaders (KOLs) actively engaging with the program, Orthocell is well positioned to secure distribution partners and establish Striate+<sup>TM</sup> as the premium dental collagen membrane.

## About Striate+™

Striate+<sup>TM</sup> (previously branded as CelGro Dental) is manufactured by Orthocell at its quality-controlled Good Manufacturing Practices (GMP) licensed facility in WA, using the Company's proprietary SMRT<sup>TM</sup> manufacturing technology, developed in conjunction with Professor Minghao Zheng and the University of Western Australia.

<sup>&</sup>lt;sup>1</sup> Referenced papers were used to derive specific assumptions in the US, EU, JP and AUS procedure potential estimates. Papers used include both US and OUS databases and studies.





Striate+<sup>TM</sup> is a premium dental membrane with market uptake driven by the surgeon's preference for high quality, easy to use devices facilitating better patient outcomes. Clinical studies have shown using Striate+<sup>TM</sup> supported transition from two-stage to single-stage dental procedures, reducing the procedure time by several months (see Figure 1). This is of significant interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures.

## Example of guided bone regeneration Single-stage dental implant procedure 1. Preparation of repair site. Defect site is filled with bone graft 2. Striate+ placed over defect and implant abutment installed 3. Wound closure 4. Crown placement 3-6 months later

Figure 1: Single stage dental implant procedure

Release authorised by Paul Anderson Managing Director Orthocell Ltd.

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## **About Orthocell Limited**

Orthocell is focused on regenerating mobility for patients bydeveloping innovative 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 orthopaedic, reconstructive, and surgical applications. CelGro has received regulatory approval in the EU, Australia and the US for bone and soft tissue regeneration in dental procedures. The Company is investigating other clinical used for CelGro™ in peripheral nerve and tendon repair. The Company's other major products are personalised cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies for Ortho-ATI® designed to assist in the US (FDA) approval process.

For more information on Orthocell, please visit <a href="www.orthocell.com.au">www.orthocell.com.au</a> or follow us on Twitter <a href="www.linkedin.com/company/orthocell-ltd">@OrthocellItd</a> and Linkedin.com/company/orthocell-ltd

