Orthocell receives first US CelGro product approval

- **Orthocell receives FDA 510(k) clearance** to market and supply CelGro for dental bone and tissue regeneration procedures
- **Striate+ registered as the new global brand for** the CelGro dental bone and tissue regeneration product
- **US, EU and AU market approvals now in place strengthens partnering potential**
- **Validates the SMRT™ manufacturing technology** and provides a pathway for additional approval in key peripheral nerve repair market

Perth, Australia; 14 January 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has achieved FDA 510(k) clearance to market and supply its CelGro collagen medical device for dental bone and tissue regeneration procedures in the US.

Orthocell Managing Director, Paul Anderson, said: "US approval has come sooner than expected and is a significant inflection point for our Company. I am excited by this strategic milestone and the positive step it represents on our pathway to partnering Striate+ in dental GBR indications. I look forward to working with our leading dental surgeons to introduce the new global brand, Striate+, previously branded as CelGro® Dental, and to make a meaningful impact in the US market."

The FDA 510(k) clearance now allows Orthocell to supply Striate+ in the US dental market, estimated at US$500 million per annum[1]. Striate+ has been approved for supply in dental bone and tissue regeneration procedures such as dental bone defect repair, augmentation around dental implants in immediate and delayed extraction sockets and guided tissue regeneration procedures in intrabony periodontal defects.

The 510(k) clearance follows the Company's application submitted to the FDA in May 2020. The FDA determined that, for the indications above, Orthocell's Striate+ is substantially equivalent to a predicate device and can therefore market Striate+ in the US. Striate+ has, based on surgeon feedback, 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.

Leading US dental surgeon, Dr Pamela Ray, commented: "Striate+ has exceptional handling qualities - when manipulating, it remains dimensionally stable and unrolls easily back to the original size. It has great tensile strength and does not deform when hydrated. I am excited by this innovative product and its potential. I believe it will assist with improving patient outcomes and I look forward to working with the team at Orthocell as it enters the US market."

[1] Referenced papers were used to derive specific assumptions in the US procedure potential estimates. Papers used include both U.S. and OUS databases and studies.

The Company will now pursue negotiations with multi-national dental companies for US 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 a distribution partner and establish Striate+ as the best-in-class dental resorbable collagen membrane.

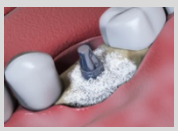
About Striate+

Striate+ (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™ manufacturing technology, developed in conjunction with Professor Minghao Zheng and the University of Western Australia.

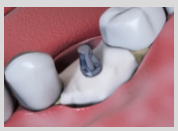
The Company believes Striate+ represents a breakthrough in dental bone and tissue reconstruction with market uptake driven by the surgeon's preference for high quality, easy to use devices facilitating better patient outcomes. Clinical studies have shown using Striate+ supported transition from two-stage 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

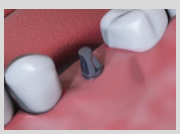
Single-stage dental implant procedure



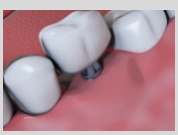
1. Preparation of repair site. Defect site is filled with bone graft



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

The CelGro Platform

US market clearance of Striate+ validates the SMRT™ manufacturing technology and provides a pathway for Orthocell to continue driving the development of CelGro® collagen medical device in the key peripheral nerve repair application. The global peripheral nerve repair market is estimated to be

worth more than US$7.5 billion per annum, with approximately 3,000,000[2] procedures that could use the nerve repair product each year.

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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 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, nerve 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. The Company's other major products are the cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is moving forward with Ortho-ATI® clinical studies designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocelltd** and LinkedIn www.linkedin.com/company/orthocell-ltd

[2] Addressable markets include US, Japanese, European and Australian markets. Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.