

MEDIA RELEASE - EMBARGOED

29 May 2023

Orthocell Launches New Bio-Manufacturing Facility

PERTH, Australia, 29 May 2023: Australian regenerative medicine company, <u>Orthocell Ltd</u>, will today officially launch a new GMP certified bio-manufacturing facility to scale up production and global distribution of its novel dental bone regeneration product, <u>Striate+ TM </u> – a significant achievement for Australia's biotechnology and manufacturing industries.

The new facility is based at the Company's headquarters (HQ) located alongside the Murdoch Health and Knowledge Precinct. It is purpose-built to scale up manufacturing from 10,000 to >100,000 Striate+ units per year, following a \$23.1 million global exclusive marketing and distribution deal secured with BioHorizons in June 2022.

Orthocell's efforts to secure a sustainable link into this valuable global med-tech supply chain, has cemented Perth's growing reputation as a leader in bio-manufacturing. A milestone worth celebrating, according to Orthocell Managing Director, Paul Anderson.

"This is a major achievement for Western Australia. Orthocell's landmark deal with BioHorizons and subsequent expansion of our manufacturing capacity represents the successful translation of quality science into a world-class product – backed by a comprehensive program of locally-run pre-clinical and clinical studies and regulatory approval in AUS, EU and the US – with other international markets to follow," said Mr Anderson.

Onsite today, Mr Anderson and the Orthocell team will be joined by the Hon. Stephen Dawson MLC. Minister for Emergency Services; Innovation and the Digital Economy; Medical Research; Volunteering – together with long standing clinical and commercial contributors, and selected patients who have personally benefited from the Company's regenerative medicine therapies.

"We are delighted to officially launch our new manufacturing facility today in the company of special guest, Minister Dawson. Attendees will be taken on a tour of the entire Orthocell HQ, which was initially supported by a \$250k government grant. Since then, it has grown into a dynamic home for Orthocell's novel biological products which optimise the repair of bone, nerve, tendon, and cartilage injuries – led by a 36-strong team in-house, with respected academic and key opinion leading (KOL) collaborators too," said Mr Anderson.

Striate+ is now approved in Australia, Europe and the US for use in guided bone regeneration around dental implants and is distinguished by its efficacy and ease of use in practice. Standout features of the new facility at the Orthocell HQ, where it is manufactured, include a dedicated state-of-the-art clean room manufacturing facility, with packaging and warehousing areas, covering over 400m². Orthocell has also welcomed four new production technicians and new senior regulatory and quality personnel to support its growing operations.

Orthocell has developed two product lines for tissue regeneration – a collagen medical device (CelGro™ Platform) to augment surgical repair of bone and soft tissue; and two autologous cell therapies used to treat injured or degenerate cartilage and tendon tissue by local implantation of the patient's own healthy cells. All products are developed and manufactured onsite at the Orthocell HQ.

Minister Dawson has commended Orthocell for focused work to translate its valuable portfolio of intellectual property into globally attractive commercial deals, which bring resources and employment home to Western Australia.





"The McGowan Government is committed to investing in our local manufacturing and biotechnology industries. Orthocell is a prime example of why we support this part of our knowledge economy, long-term," said Minister Dawson.

"Today's launch is a chance to celebrate the expansion of the Orthocell HQ and its status as a respected, local biotechnology company. It's also an opportunity to mark the shared achievements of government, academic institutions, investors and the wide network of other supporters who continue to back this incredibly vibrant sector, which is ripe with opportunity."

For more information about Orthocell, visit orthocell.com.

- ENDS -

MEDIA

The media is invited to attend the launch of Orthocell's new bio-manufacturing facility:

- When: 2:45pm, Monday 29 May 2023
- Where: Orthocell HQ, Building 191 Murdoch University, South Street, Murdoch WA 6150
- Parking: Parking onsite, Carpark 11
- VIP Guests and Spokespeople: 1. Hon. Stephen Dawson MLC. Minister for Emergency Services; Innovation and the Digital Economy; Medical Research; Volunteering. 2. Orthocell MD, Paul Anderson.
- RSVP / MEDIA CONTACT: H^CK Director, Haley Chartres, m. +61 423 139 163, e. haley@hck.digital

ABOUT ORTHOCELL

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 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.

