OCC to Launch Third Revenue Generating Product in SmrtGraft™ for Tendon Repair

- **Orthocell submits TGA application for approval to commence sales of its SmrtGraft™ Product in Australia, which is used for tendon repair and regeneration applications**
- **Submission follows positive results from its tendon regeneration study indicating that SmrtGraft reduces the rate of treatment failure and the need for revision surgeries**
- **SmrtGraft will be the third revenue generating product to be launched by the Company, in addition to Striate+™ (for dental bone regeneration) and Remplir™ (for peripheral nerve repair) which are already in market**
- **Significant addressable market for SmrtGraft, estimated to be worth more than US$1.2 billion annually, with >800,000 surgical repairs of RC tendons alone completed in just the AUS, USA and EU per year[1]**
- **Geographical roll-out strategy for tendon and ligament repair devices in progress, starting with Australia and other key regulatory jurisdictions to follow**

Perth, Australia; 11 June 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has applied to the Therapeutic Good Administration (TGA) for Australian market approval for its SmrtGraft™ tendon repair device, in preparation for its introduction into the Australian tendon repair and regeneration market.

Orthocell Managing Director, Paul Anderson, said: *"We are delighted to announce the Australian regulatory application for our SmrtGraft tendon repair product. Australia is an important stepping stone to other very large and attractive international target markets, including the USA. This is another significant milestone in our product expansion strategy. Once approved, it will be Orthocell's third revenue generating medical device available in Australia."*

The regulatory application follows positive results from its tendon regeneration study, published in the highly regarded Journal of Orthopaedic Translation in 2021. In this prospective case series study of 18 patients, the safety and effectiveness of SmrtGraft, when used to augment the surgical repair of rotator cuff tendons (see Figure 1), was assessed. Participants in the study had previously suffered full thickness tears of the rotator cuff tendon in the shoulder, following work-related, motor vehicle or sporting incidents. As a result of their injury, patients experienced chronic pain and difficulty performing basic activities of daily living (i.e. sleeping, bathing and dressing), playing sport and/or working.

All patients in the study achieved successful tendon repair, with significant improvements in pain, function and quality of life. None of the participants required further surgery for a re-tear of the rotator cuff tendon – an important finding since revision surgeries for re-tears is reported to occur in up to 57%[2] of cases.

[1] Company estimates based on published literature and other publicly available sources

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

The SmrtGraft™ Advantage and market size

SmrtGraft is used as a wrap or to cover surgically repaired tendons (Figure 1). It is intended to protect the tendon and promote tendon cell migration and proliferation at the repair site. Providing a favourable microenvironment at the repair site improves tissue healing and quality of the repair.

Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015 found that large rotator cuff repairs regularly tear again at a rate of up to 57%. The lack of revision surgery reported in the SmrtGraft study provides confidence that using SmrtGraft™ to augment the tendon repair will reduce incidence of treatment failure by reducing the high re-tear rate associated with the commonly used surgical approach.

While the SmrtGraft study focussed on repairs to the rotator cuff tendon, the product has the potential to be used in multiple tendon applications in addition to the rotator cuff, including tendons in the knee, hip, ankle, elbow, wrist and hands.

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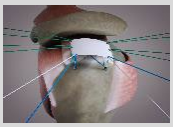
Special Access Scheme

SmrtGraft is currently not listed on the Australian Register of Therapeutic Goods (ARTG). Patients treated with SmrtGraft have been approved by the TGA via its Special Access Scheme (SAS).

Example of surgical repair of the rotator cuff tendon augmented with SmrtGraft

1. Tendon Tear
Tendon detached from bone and retracted at tear site

2. Preparation of Repair Site
Torn tendon trimmed and sutures anchored in healthy bone



3. Apply SmrtGraft
Customised to size and placed over repair site to promote tendon healing

4. Reattachment
Tendon and SmrtGraft secured in place with sutures

Figure 1 Surgical repair of the rotator cuff tendon augmented with SmrtGraft

Next Steps

SmrtGraft is manufactured by Orthocell at its GMP (Good Manufacturing Practice) facility in Western Australia (WA), using the Company's proprietary SMRT™ manufacturing technology. As with the Company's other approved medical devices, Striate+™ for dental bone regeneration, and Remplir™ for peripheral nerve repair,

the Company believes SmrtGraft will become a leading tendon repair device, with uptake driven by the surgeon's preference for high quality, easy to use devices that facilitate better patient outcomes.

The Company is well-positioned to achieve further international approvals for SmrtGraft in tendon and ligament repair – a key growth area for our business. Planned geographical roll out starts with Australia, with approvals in other key markets to follow.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

For more information, please contact:

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

About Orthocell Limited

ACN 118 879 135
Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

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.