Remplir™ Study Delivers Compelling 81% Success Rate

Data to support US sales roll out and EU + UK regulatory submissions

- **Interim results from a new Remplir™ study demonstrated a compelling overall treatment success rate of 81.1% following nerve repair procedures.**
- **Real World Evidence (RWE) patient data collected in the study confirms Orthocell's nerve repair product, Remplir, as the ideal medical device for connecting severed nerves, protecting damaged nerves, or capping nerve ends after amputation.**
- **The data demonstrated:**
  - **81.2% of muscles innervated by repaired nerves achieved functional motor recovery.**
  - **89.5% of nerve decompression procedures resulted in significant improvement or complete relief of symptoms.**
  - **No post-treatment complications or adverse reactions to Remplir were reported in any patient.**
  - **Results consistent with previously published clinical trial outcomes.**
- **The data confirms the superior and predictable outcomes that Remplir delivers and is testament to why over 200 surgeons across more than 165 hospitals (and growing) are now using the product.**
- **Study data will be an important addition to Orthocell's medical education efforts in US sales roll out and provide supporting evidence for the EU + UK regulatory submission expected in Q4 CY25.**
- **Orthocell ultimately targeting a Total Addressable Market ("TAM") in selected jurisdictions in excess of US$3.5 billion[1].**
- **Internal resources remain focused on the Remplir rollout in the US$1.6 Billion U.S. market[2], with in-country representatives making significant progress working with distributors to gain hospital approvals, on-board surgeons and establish active accounts. Initial US surgical cases continue to build.**

Perth, Australia; 08 September 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce interim results from a new Remplir multi-centre post-market clinical follow-up study ("Remplir Real World Evidence study" or "Remplir RWE Study"). **The overall treatment success rate for all procedure types included in the study was a compelling 81.1%.** The Remplir RWE Study will be used by Orthocell to support US Remplir sales roll out and the regulatory submissions in the UK and EU, which is expected to be submitted late Q4 CY25.

This interim analysis demonstrates the utility of Remplir in surgical procedures for a range of peripheral nerve conditions, including restoration of hand function after cervical spinal cord or brachial plexus injury, and relief of symptoms in chronic nerve injuries such as carpal tunnel syndrome. Importantly, the results are consistent with the compelling clinical trial outcomes previously published in the *Journal of Reconstructive Microsurgery Open.*

[1] Company estimate of addressable market size for Remplir (AUS, NZ, SGP, USA, EU/UK, CAN, BRZ, JAP & THA). Sources include iData Research Inc and other publicly available market research reports and published literature.

[2] USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

The Remplir RWE study is designed to collect and analyse treatment outcomes generated during the routine clinical practice of nerve repair procedures. RWE is an increasingly valuable contributor to regulatory decision-making, as it provides evidence of product safety and performance from everyday clinical settings, in contrast to the carefully controlled patient populations and conditions of clinical trials.

The Study was conducted in collaboration with Dr Alex O'Beirne at the Western Orthopaedic Clinic; A/Prof Matthew Lawson-Smith at the Murdoch Orthopaedic Clinic; and Jaslyn Cullen at Innervate Occupational Therapy, and Hand Works Occupational Therapy.

Orthocell CEO and MD, Paul Anderson, said: "*We are delighted with the interim results from our Remplir RWE Study, validating the superior Remplir clinical outcomes, previously published in a highly regarded, peer reviewed journal. This performance is why more than 200 surgeons across more than 165 hospitals are now using Remplir and these numbers continue to grow.*

"This data is incredibly valuable from a commercial and regulatory perspective as it demonstrates the performance of Remplir across a heterogenous patient population in the real world, as distinct from a tightly controlled clinical trial environment.

"It is imperative that we continue to collect performance data to drive the rapid market adoption in the US and support the EU & UK regulatory applications."

Remplir RWE Study Overview

The Remplir RWE study is an ongoing, multi-centre prospective and retrospective post-market clinical follow-up study being conducted in Australia (ACTRN12624001213538). The study is designed to collect safety and efficacy data on the use of Remplir in a real-world setting. Patients are eligible for inclusion in the study if they receive Remplir during any peripheral nerve procedure at a study site. Procedures ranged from complex nerve transfers and lower limb nerve repairs to more common surgeries used to treat carpal tunnel syndrome.

The study population includes patients with acute traumatic nerve injuries (e.g. motor vehicle, work-related and sporting accidents), and chronic nerve injuries (e.g. carpal or cubital tunnel syndrome). Patients seek surgical treatment because their nerve injuries cause significant issues, such as muscle paralysis, pain, numbness, or burning/tingling sensations. The study collects data on outcomes related to the goals of surgical treatment (e.g. restoration of hand function after cervical spinal cord injury, relief of symptoms caused by carpal tunnel syndrome) for up to 24 months after treatment with Remplir.

Study Results

Data on 49 patients, aged 14 to 82 years, was included in the interim analysis. The patients underwent a total of 67 peripheral nerve procedures, most commonly in the upper limb (82%). The majority (61.2%) were nerve reconstruction procedures for acute injury (including nerve transfer and nerve grafting), and 38.8% were nerve decompression procedures using Remplir as a protective wrap in patients with chronic nerve injuries.

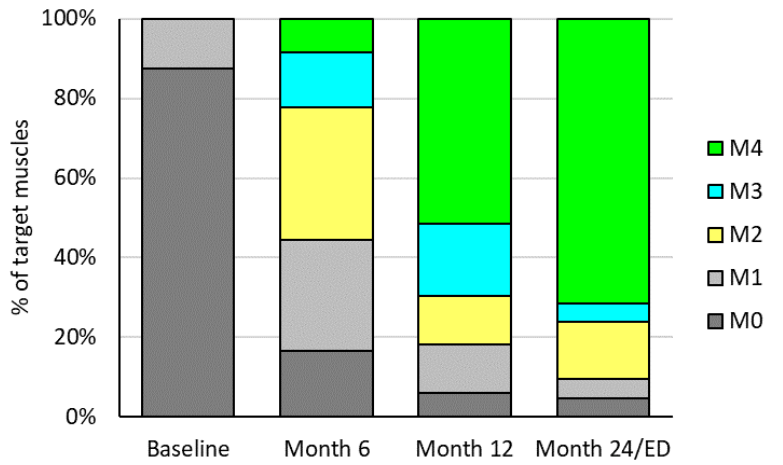
Safety data was available for all 67 procedures, and no post-treatment complications or adverse reactions to Remplir were reported in any patient. Performance data was available for 43 procedures (53 therapeutic targets[3]). **The overall treatment success rate for all procedure types was 81.1% (43 of 53 therapeutic targets). Results are summarised by the main procedure types below.**

Motor nerve reconstruction

[3] Therapeutic target depends on procedure. Therapeutic target for motor nerve reconstruction is the muscle, and one reconstruction may innervate more than one muscle. Therapeutic target for nerve decompression is relief of symptoms.

A total of 12 participants, who received motor nerve reconstruction in 22 nerves, provided data for assessment of motor recovery. Motor recovery was assessed by grading the strength of target muscles controlled by the repaired nerve, according to the British Medical Research Council Grading System (MRC grade). **Results showed that 81.2% (26 of 32) of all target muscles reached functional recovery, which was achieved at an average of 8.3 months after surgical treatment with Remplir**. Figure 1 summarises motor recovery grading at each study time point.

Figure 1 – Recovery of Muscle Power in Patients undergoing nerve reconstruction



Grade M3 and M4 – voluntary movement with improved strength and range of motion. Maximum level of recovery expected.

Grade M2 – voluntary movement restored, limited strength and range of movement.

Grade M0 or M1 – no voluntary movement.

Nerve decompression

Nineteen participants provided study data on nerve decompression procedures using Remplir. This included 8 carpal tunnel revision surgeries, and 7 cubital tunnel releases (2 revisions). Treatment success was assessed by grading of symptoms compared to pre-surgery as: completely relieved, significantly improved (most symptoms resolved), unchanged, or worse. **Results showed that 89.5% (17 of 19) of nerve decompression procedures resulted in significant improvement or complete relief of symptoms after treatment. No patients required additional surgical treatment during follow up.**

Significance of Study results and next steps

Considering these study results, published clinical data, and the rapid product adoption in existing markets, Orthocell believes Remplir has the potential to redefine the global nerve repair market and rapidly become the new gold standard in nerve repair surgery to return function to paralysed limbs and provide relief of symptoms. Interim study results will be presented at key medical conferences and the study continues in the recruitment phase.

With circa $27 million in cash and no debt, Orthocell is well-positioned to drive rapid product adoption to deliver a step change in revenue in FY26. The Company is also accelerating the launch of Remplir in Canada and remains on schedule to submit its EU/UK application in Q4 CY25.

Release authorised by:
Paul Anderson
Orthocell Ltd CEO and MD

For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited
CEO and MD
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

Investor enquiries

Shaun Duffy
VECTOR Advisors
P: +61 404 094 384
E: sduffy@vectoradvisors.au

About Orthocell Limited

ACN 118 897 135

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 a 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 the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed 14 US distributors and recorded initial sales. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore where it is distributed by Device Technologies Group. Other Remplir approvals include Thailand and Canada. 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.