New Study Confirms Superiority of Remplir™ Over Standard Nerve Repair Technique

Compelling data to underpin competitive advantage ahead of US sales roll out

- **New study demonstrates that nerve repair with Remplir results in superior regeneration of nerve tissue and earlier return of muscle function, compared to current standard of care, which involves suture-only repair.**
- **Use of Remplir allows surgeons to reduce the number of sutures required to reconnect severed nerves - sutures result in adverse tissue reactions and compromises nerve regeneration.**
- **Compelling study results will form a cornerstone of medical education efforts in US sales roll out following formal presentation at key upcoming medical conference.**
- **Orthocell ultimately targeting a Total Addressable Market ("TAM") in selected jurisdictions in excess of US$3.5 billion[1], with the current TAM in markets where Remplir is approved already equating to US$1.8 Billion[2].**
- **Internal resources remain focused on the Remplir rollout in the US$1.6 Billion US market[3], with in-country representatives making significant progress towards imminent first sales and first US surgical use of Remplir.**
- **Existing cash reserves of circa $30 million see the Company fully funded for the Remplir global roll out.**

Perth, Australia; 19 June 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce interim results from a new study evaluating the impact of sutures on nerve regeneration and functional recovery in surgical repair of severed peripheral nerves ("Suturing Study" or "The Study"). The Suturing Study was commissioned by Orthocell to support US Remplir sales roll out and was conducted in collaboration with Orthocell's Chief Scientific Officer ("CSO") and highly regarded physician, Professor Minghao Zheng, and the University of Western Australia. The compelling interim results indicate that nerve repair with Remplir™ supports earlier restoration of nerve function and superior regeneration of high-quality nerve tissue compared to standard of care suture-only repair.

Orthocell CEO and MD, Paul Anderson, said: "*We are delighted with the results from our Suturing Study, validating the superior Remplir clinical outcomes, previously published in a highly regarded, peer reviewed journal. These Study results provide key data to support the U.S. product sales roll out and rapid market adoption and will be a cornerstone of our US medical education efforts. We believe Remplir will redefine the nerve repair market and vastly improve the success of often complex nerve repair surgery.*"

Suturing Study Overview

The use of sutures to reconnect severed nerves is the global standard of care in peripheral nerve repair surgery and account for circa 90% of the 700,000 nerve repair procedures performed in the US each year. However,

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

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

despite over 50 years' experience with this surgical technique, outcomes from peripheral nerve repair procedures remain inconsistent and unpredictable. An emerging body of evidence suggests that adverse tissue reaction to suture material may be a significant contributing factor in poor clinical outcomes after peripheral nerve repair. Animal studies have shown that an inflammatory reaction to sutures results in scar tissue formation that impedes nerve regeneration across the repair site and prevents the nerve from gliding freely during movement. Use of Remplir has allowed surgeons to reduce the number of sutures needed to stabilize the reconnected nerve ends, leading to improvements in consistency and predictability of clinical outcomes

The Study was conducted using an established rat sciatic nerve injury model. Repair of surgically severed nerves was evaluated in 48 rats across 4 treatment groups: (i) repair using 1 suture, (ii) repair using 3 sutures, (iii) repair using 6 sutures, and (iv) repair using 1 suture augmented with Remplir. Nerve function and regeneration were evaluated up to 12 weeks post-treatment.

Interim Study Results

In this study, earlier restoration of nerve function and regeneration of high-quality nerve tissue were observed in the Remplir group compared to suture-only repair (see table below). There was no evidence of adverse reaction to Remplir, consistent with Remplir's established history of superior biocompatibility in thousands of procedures already undertaken. However, histological evaluation of nerve tissue in the suture-only groups showed consistently severe inflammation and foreign body response adjacent to the suture material. Use of Remplir appeared to mitigate the inflammatory reactions to suture material, thereby reducing the risk of scarring that could compromise nerve regeneration, nerve gliding, and ultimately, functional outcomes.

These results provide evidence that supports the positive outcomes of previous animal and human studies of Remplir.

Effect of Repair on nerves	Repair with Remplir	Current standard (sutures)
Early return of function	**Yes**	**No**
Significantly higher sciatic functional index (SFI) scores (a measurement of the return of muscle function) were observed in the Remplir-repaired group at 2 weeks post-treatment compared to the suture only groups. Physical disruption of nerve structure and inflammatory response caused by the suture material resulted in poorer quality nerve regeneration most likely responsible for the significantly slower functional recovery observed in the suture only groups.		
Higher quality nerve regeneration	**Yes**	**No**
Histological evaluation of nerve tissue in the Remplir-repaired group showed better cellular and fascicular alignment within the repaired nerve tissue. In the suture-only groups, misalignment of the nerve ends and extrusion of nerve fascicles through the compromised epineurium was common and exacerbated by increasing numbers of sutures.		
Restoration of nerve structure	**Yes**	**No**
Remplir promoted earlier establishment of blood vessels within the regenerating tissue and re-establishment of the protective soft tissue around the nerve, which provides crucial cushioning for the nerve and facilitates free gliding of the nerve during movement. In the suture-only groups, the nerve's protective outer layer (the epineurium) was significantly damaged, resulting in exposure of delicate regenerating nerve tissue at the surgical site.		
No inflammatory response	**Yes**	**No**
Suture materials triggered a foreign body reaction that was still present at 12 weeks post-treatment. Prolonged inflammation results in scarring that can block nerve regeneration across the repair site. This foreign body reaction was absent in repairs performed with Remplir.		

Orthocell CSO, Professor Minghao Zheng, said: *"Use of Remplir did not induce inflammation or scarring, resulting in better nerve regeneration. This outstanding local tissue response, combined with its optimal handling qualities, are key advantages of Remplir in nerve repair surgery. Use of Remplir will help surgeons to simplify the repair process, facilitate high quality nerve regeneration, and ultimately provide consistent and predictable outcomes to patients and support their return of function goals."*

Significance of Study results and next steps

In light of 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. Interim study results will be presented at an upcoming key medical conference with final study results to be released and prepared for publication.

With circa $30 million in cash and no debt, Orthocell is well-positioned to successfully complete first US sales and 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 its first 12 US distributors, with first sales expected to follow shortly. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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.