

Compelling 85% success rates from Remplir™ nerve repair study published in peer-reviewed clinical journal

- Peripheral nerve repair clinical study showing consistent return of muscle function to paralysed upper limbs, following nerve repair with Remplir™, now published in peer-reviewed Journal of Reconstructive Microsurgery Open.
- Results showed 85% (23 of 27) of nerve repairs with Remplir, at 24 months post treatment, resulted in functional recovery of muscles controlled by the repaired nerve.
- Compelling outcomes confirm Orthocell's nerve repair product, Remplir, as the ideal medical device for the connecting of severed nerves, protecting damaged nerves or capping amputated nerves.
- Top-line results from US FDA Remplir nerve repair study are expected in Q3 CY24, and Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 with progression into sales soon thereafter.
- Publication will likely significantly raise the profile of Remplir with potential partners, practitioners and patients where the Company has the potential to become the leading device in the US in an addressable market estimated to be worth more than US\$1.1 billion per annum¹.

Perth, Australia; 30 April 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the publication of results from the Remplir™ nerve regeneration clinical trial ("Remplir study") - showing nerve repair with Remplir following injury to the spinal cord, brachial plexus and other peripheral upper limb nerves - consistently restores arm and hand function.

The previously announced findings represent a substantial advance in peripheral nerve repair and the use of novel medical devices in surgical treatments for patients suffering from upper limb paralysis.

The study was published in the Journal of Reconstructive Microsurgery Open ("JRMO"), a peer-reviewed clinical journal renowned for sharing advances in nerve reconstructive techniques and regeneration. The publication follows a successful collaboration between Dr Alex O'Beirne at the Western Orthopaedic Clinic; Jaslyn Cullen at Jaslyn Cullen Occupational Therapy, Bone and Brain Group at the Perron Institute for Neurological and Translational Science; and Orthocell's inventor and Chief Scientific Officer, Professor Minghao Zheng at the Perron Institute and the University of Western Australia. The publication may be viewed here: [Remplir Publication](#).

Orthocell Chief Scientific Officer, Professor Minghao Zheng, said: "This study validated Remplir's unique mechanism of action mimicking the native structure of epineurium, providing a protective barrier and neurotrophic microenvironment for nerve regeneration. Remplir's unique biological characteristics underpinned the consistent return of function to paralysed upper limbs, the primary goal in this study. We are delighted to see this compelling research now published in JRMO and look forward to working with surgeons to consistently return muscle function following Remplir nerve regeneration treatment."

¹ US addressable market estimate was developed by the Company using reports from US healthcare databases and referenced papers of studies conducted both within and outside the US.

Peripheral nerve injuries and repair

Peripheral nerve injuries, caused by trauma, surgical procedures, and degenerative disorders, are a common clinical problem worldwide. Peripheral nerve injuries often affect the upper limb and can cause intractable neuropathic pain, paralysis, and a lifelong impact on patients' quality of life. Nerve conduits were introduced to assist surgeons to reduce the use of damaging sutures and to reconnect and protect severed and damaged nerves. Studies show that most of the current available conduits are rigid and difficult to shape, with specific diameters not always appropriate for the coaptation site and can result in suboptimal return of sensory and motor function.

Study objectives

The purpose of the Remplir™ study was to evaluate the biological characteristics and clinical performance of Remplir in the reconstruction of upper-extremity peripheral nerve injuries. Nineteen patients aged between 18 and 50 years were recruited for the study. A total of 36 peripheral nerve reconstructions were performed using either nerve transfer or nerve grafting. Patients in the clinical trial suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents, resulting in partial or total loss of use of their arms and, in more severe cases, their legs and torso as well (quadriplegia). Patients experienced significant pain and were unable to perform basic activities of daily living (i.e. eating, bathing, dressing and toileting), play sport and/or work. Without surgery they would not have regained normal use of their injured arm and hand.

Study results

Patients received one or more nerve repairs augmented with Remplir in one or both upper limbs. Recovery after treatment was assessed by grading the strength of target muscles² closest to the site of nerve repair. Follow up data at 12 months was available for 16 of 19 patients involving 33 nerve repairs. Results showed 76% (25 of 33) of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve. Follow-up data at 24 months treatment was available for 14 of 19 patients involving 27 nerve repairs. Results showed that 85% (23 of 27) of nerve repairs resulted in functional recovery of target muscles closest to the repair site. **The results demonstrate that functional gains were not only maintained but continued to improve between 12- and 24-months post-treatment.**

The Remplir Advantage

Remplir is manufactured by Orthocell at its quality-controlled facility in WA, using the Company's proprietary SMRT™ manufacturing technology. Remplir is available in Australia and New Zealand for use in the surgical repair of peripheral nerve injuries and is included on the Australian Prostheses List (PL). Inclusion on the PL enables patients to receive reimbursement from private insurers for the use of Remplir in peripheral nerve repair procedures, reducing costs to the patient.

The Company appointed Device Technologies (DVT) as the exclusive distributor of Remplir across Australia and New Zealand in September 2022 and launched the product in November 2022, with a focus on supplying existing orthopaedic and plastic reconstructive KOL accounts. The ramp up of product sold in the ~18 months since market launch is gaining traction with 100+ orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries, from facial to upper and lower limb nerves, across Australia and New Zealand.

² British Medical Research Council Grading System (MRC grade), with a score of 0 to 5. A score of zero (0) indicates no nerve connection to the muscle (i.e., no recovery), a score of five (5) is given to muscles with normal power/strength. A score of 3 or better is clinically defined as a meaningful functional recovery.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

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About Orthocell Limited

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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 its 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.