Orthocell gears up for the commercialisation of Remplir™ in the US with the appointment of two key US based Executives

- **Orthocell has appointed two experienced US-based executives, John Walker and Phillip Edmondson, to drive the market launch and sales of Remplir™ following the expected US FDA approval in the first quarter of 2025**
- **Collectively, Mr Walker and Mr Edmondson bring over 19 years' experience, specifically in the US nerve repair sector, having both previously worked with the highly respected medical device company Axogen**
- **Mr Walker and Mr Edmondson will lead medical affairs, sales strategies and account management in the key US$1.6 Billion[1] market**
- **Mr Walker is a highly experienced sales executive, who has successfully led global product launches and sales strategies, most notably helping to lead the growth of nerve repair device sales at Axogen**
- **Mr Edmondson is an award-winning medical affairs professional, who excels in creating product awareness, building advocacy and implementing successful medical education programs, that contribute to sales growth**
- **Orthocell has a strong balance sheet with circa $35 million in cash to drive the US market launch, along with expansion into other key markets including Singapore, Southeast Asia, Canada and the EU/UK**
- **Orthocell remains on schedule to release top-line results from its Remplir US market authorisation study and submit its Remplir US 510(K) application in Q4 CY24, with progression into US FDA approval and sales soon thereafter.**

Perth, Australia; 11 November 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the appointment of two key US-based executives to support Orthocell's US market launch of its revolutionary nerve repair product, Remplir™.

Remplir is now a well proven product with rapidly growing sales in the Australian and New Zealand markets, with a growing number of surgeons praising its unique repair qualities. Orthocell has been actively preparing for its US launch for some time, with surgeon and distributor engagement well advanced. US 510(K) market authorisation is expected in Q1 CY 2025 with sales to commence in the substantial US$1.6 billion market soon thereafter.

Orthocell CEO and MD, Paul Anderson, said: *"The Remplir launch in Australia has proven to be a great success, with over 150 surgeons now using the product and rapidly growing sales. The USA provides a significant opportunity for our company as a circa $US 1.6 billion market, and our belief is that it will quickly become our single largest market. Over the last two years, we have been working closely with US surgeons, Centres of Excellence and leading research institutes to prepare for US FDA approval and market launch. We are delighted to have John and Phillip join us to lead the US launch and are excited about the next phase of growth. With all the preparation we've been conducting in the background, we expect revenue growth and surgeon adoption of Remplir to accelerate from market clearance."*

In preparation for the expected US regulatory clearance by the FDA in Q1 CY25 and formal entry to the United States medical device market, Orthocell has secured the services of two highly experienced sales and medical affairs executives, John Walker and Phillip Edmondson. Mr Walker and Mr Edmondson bring over 19 years'

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

experience specifically in the US nerve repair sector and were formerly employed by Axogen, one of the major US suppliers of medical devices for peripheral nerve repair. Mr Walker and Mr Edmondson will lead medical education, sales and account management in the key US$1.6 Billion[1] market. With this appointment, Orthocell has cemented its commitment to its US expansion strategy for Remplir.

John Walker, Vice President - Sales

Mr Walker is a high-performing sales executive with over 25 years' experience in various senior salesforce leadership and operational roles in the orthopaedic, primarily peripheral nerve repair, medical device sector. Most recently, Mr Walker was the Area Vice President and Director of Sales for USA and Europe at Axogen. Mr Walker was one of the highly awarded leaders at Axogen, leading the growth of nerve repair device sales. Mr Walker is based in Texas and will commence US launch preparations immediately.

Phillip Edmondson, Vice President - Medical Affairs

Mr Edmondson is an experienced medical affairs and sales executive with over 18 years' experience in various senior medical device sales and education roles in the medical device, pharmaceutical, and biologics sectors. Mr Edmondson was the Senior Medical Affairs Manager and Sales Account Manager at Axogen where he developed, implemented, and monitored Axogen's academic program strategy. Mr Edmondson was the primary liaison with academic institutions, Residency and Fellowship Directors, surgical trainees and key opinion leaders (KOLs) and received multiple awards and recognition for his outstanding sales growth performance and leadership. Mr Edmondson is based in Florida and will commence US launch preparations immediately.

With circa $35 million in cash and no debt, Orthocell is well positioned to successfully launch Remplir in the United States and other key markets including Singapore, Southeast Asia, Canada and the EU/UK. Importantly, the Company remains on schedule to release top-line results from its Remplir US market authorisation study and submit its Remplir US 510(K) application in Q4 CY24, with progression into US FDA approval and sales soon thereafter.

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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 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 US FDA (510k), Australia (ARTG), New Zealand (WAND), UK (UKCA Mark) 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.