

ASX Announcement

Orthocell Appoints Exclusive Remplir™ Distributor for Hong Kong

Key Component of Asian Commercialisation Strategy

- Highly-credentialed medical device distribution company MontsMed appointed as the exclusive incountry distributor of Remplir™ in Hong Kong.
- First surgical cases and sales in Hong Kong expected in the near term.
- Asia represents a key strategic pillar within Orthocell's target Total Addressable Market, valued at over US\$3.5 billion¹ across selected global jurisdictions.
- Approval in Hong Kong represents a major growth opportunity for Orthocell to extend its reach through MontsMed with potential access to another nine cities and a population of around 100 million in the Guangdong-Hong Kong-Macao Greater Bay Area.
- To complement Orthocell's activity in Hong Kong, sales and surgical case momentum continues to build in Singapore via exclusive distributor Device Technologies Asia, and commencement of sales in Thailand is anticipated in 2026, with selection of an in-country distributor in Thailand in progress.
- The recently appointed Australian-based Commercial Director will oversee Remplir commercialisation and distributor management in Australia and Asia.
- The distribution appointment in Hong Kong closely follows the appointment of the Company's first distributor in the US\$75 million² Canadian market, which is also expected to generate first sales by end of CY25.
- The Company is executing its global commercialisation strategy according to plan as growth in existing markets continues and new markets are added, supported by a strong balance sheet of over \$50 million in cash.

Perth, Australia; 29 October 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the appointment of medical device distributor MontsMed as its exclusive in-country distributor for Remplir in Hong Kong. The Company expects the first surgical cases and sales in Hong Kong in the near term.

As a recognised leader in medical services across Asia, Hong Kong is considered a strategically valuable component of the Remplir global footprint. Approval in Hong Kong is key to the Company's continued expansion plans for Remplir in Asia, providing a pathway to market access in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) via the Regulatory Innovation and Development of Pharmaceutical and

^{1&}amp;2 Nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies.



Medical Device work plan. This framework allows designated healthcare institutions in the GBA to import Hong Kong–registered medical devices for urgent clinical needs. Covering nine cities and a population of around 100 million, the GBA presents a major growth opportunity for Orthocell to extend its reach through the existing distribution partnership in Hong Kong. The use of Remplir in the GBA will be subject to individual healthcare institutions applying for and receiving approval from the Guangdong's Medical Products Administration.

The commencement of Remplir sales in Hong Kong will complement the sales and surgical case momentum building in Singapore. Orthocell appointed Device Technologies Asia as the exclusive incountry distributor in Singapore, and all surgical cases undertaken to date have been sourced from the relationships held by their dedicated specialist sales team with leading plastic reconstructive and orthopaedic surgeons.

In addition to Hong Kong and Singapore, Orthocell has regulatory approval for Remplir in Thailand and is in the process of evaluating local on-the-ground specialist distributors to drive sales in the local market. The Company has built significant experience working with local distributors across both its Remplir and Striate+ products in multiple global jurisdictions and is well-placed to appoint an appropriate distributor for Remplir in these Asian markets.

Distributor appointments will continue to be made on a country-by-country basis, with partners selected for their on-the-ground expertise and relationships with leading surgeons. The Asian distributor network will be managed and overseen by the newly-appointed Commercial Director, which is an internal, Australia-based resource dedicated to driving the commercialisation of Remplir across Asia, Australia and New Zealand. Mr Hamish Thrum has been appointed to this role, having recently returned to Australia after 13 years in Singapore where he held senior commercial positions at Johnson & Johnson, Smith & Nephew, and Orthopaedic start-up organisation Zeda. Mr Thrum's knowledge of the ANZ & APAC region and contacts with key surgeons and distributors will be invaluable as Orthocell launches in Hong Kong and continues to expand the Asian footprint of Remplir in the coming years.

Orthocell CEO and MD, Paul Anderson, said: "We are approaching the commercialisation of Remplir in Asia on a country-by-country basis in a very deliberate and considered manner. The appointment of MontsMed as our exclusive distributor in Hong Kong is a key step in our Asian commercialisation strategy.

We initially identified Singapore, Hong Kong and Thailand as our primary targets in Asia. With regulatory approvals achieved and distributors now in place in two of three markets, we are focused on strategies to achieve market penetration in those countries.

It makes sense for us to continue to appoint in-country distributors in each of these Asian markets as they hold direct relationships with surgeons and hospitals. We have made the decision to appoint a Commercial Director to drive this program. Hamish Thrum brings strong Asian medical sales experience to focus on driving this process and we welcome him to the Orthocell senior executive team."

Remplir is a collagen wrap used in nerve repair surgery to assist surgeons to improve outcomes in the repair and regeneration of damaged nerves. Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US\$3.5 billion¹. The Company has a strong balance sheet with ~A\$53 million cash at bank and no debt and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets.



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: paul.anderson@orthocell.com

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163 E: <u>haley@hck.digital</u>

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+TM 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. RemplirTM, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed a network of 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, Hong Kong and Canada. SmrtGraftTM, 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 @Orthocell.ltd 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.

