CelGro® US 510(k) submission completed

- **Orthocell submits US FDA regulatory application for CelGro® for dental guided bone and soft tissue regeneration applications**
- **Submission follows positive results from its US FDA guided bone regeneration study, a key component of the FDA submission to gain US market approval**
- **CelGro®'s addressable market in dental restoration is estimated to be worth more than US$1 billion per annum**

Perth, Australia; 12 May 2020: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has completed a submission to the US Food and Drug Administration (FDA) seeking 510(k) clearance for marketing its CelGro® product for dental guided bone and soft tissue regeneration applications.

Orthocell Managing Director, Paul Anderson, said: "This is a significant milestone for Orthocell as we drive our innovative regenerative medicine products into the US, the largest global healthcare market. We are in a strong position to gain US approval and are actively progressing our US market launch strategy."

The US 510(k) submission follows positive results from its US FDA guided bone regeneration study showing CelGro® is effective in facilitating bone regeneration when used in conjunction with bone substitute and a dental implant. The Study provided critical regulatory data and is a key component of the US regulatory submission.

Dental implants are an effective and rapidly growing area of orthodontic treatment. CelGro®'s dental bone regeneration addressable market is estimated to be worth more than US$1B[1]p.a., with approximately 4.3 million procedures that require dental membranes completed each year. Market demand is expected to be underpinned by an ageing population, significant growing demand for dental therapies and surgeons' preference for quality and functional bio-absorbable membranes.

The US 510(k) submission compliments our current regulatory submission in Australia for dental bone and soft tissue regeneration applications and will be followed by submissions to the US, EU and Australia for CelGro® for repair of crushed or severed nerves and augmentation of tendon repair.

Orthocell is well positioned to execute on its partnering strategy underpinned by CelGro®'s distinct competitive advantages over existing dental membranes, particularly in the areas of cell biocompatibility, handling qualities and the promotion of high quality guided bone and tissue regeneration.

[1] iData Research report focusing on European dental barrier membrane market. Data used to estimate incidence for other regions (US, Japanese and Australian) and cross checked with other local research reports and key opinion leader feedback.

About CelGro® dental bone and soft tissue regeneration

CelGro® is a collagen medical device platform for bone and soft tissue regeneration and repair applications manufactured by Orthocell at its quality controlled Good Manufacturing Practices (GMP) licensed facility in Western Australia. Orthocell has received market authorisation (CE Mark) of CelGro® in the EU for dental bone and soft tissue regeneration applications and is actively progressing its clinician advocacy program to expand the network of referring clinicians and product use in centres of excellence.

The traditional two-stage dental implant procedure involves two separate surgical procedures and can take up to eight months to complete. CelGro® has shown to facilitate a more predictable and rapid bone regeneration underpinning a reduction in the traditional two-stage dental implant procedures to four to six months. CelGro®'s superior bone regeneration qualities have also enabled single stage procedures, avoiding a second surgery and anaesthetic by placing the implant and abutment in the jaw at the same time, completing dental implant treatment in as little as four months.

CelGro® accelerates regeneration of high quality bone and facilitates the reduction in the timeframe to complete dental implant procedures (see Figure 1). This is of significant clinical interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures.

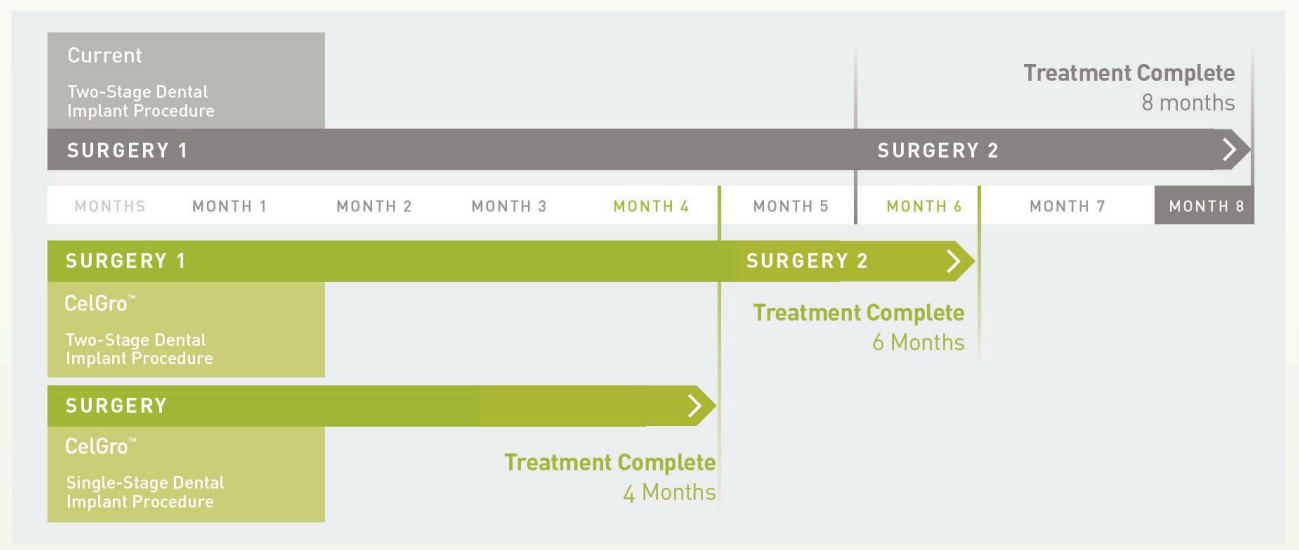

Figure 1: CelGro® accelerates dental implant procedures

Release authorized by:
Paul Anderson
Managing Director, Orthocell Ltd

[1] iData Research report focusing on European dental barrier membrane market. Data used to estimate incidence for other regions (US, Japanese and Australian) and cross checked with other local research reports and key opinion leader feedback.

For more information, please contact:

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director
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

About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of soft tissue injuries. Orthocell's portfolio of products include CelGro® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro® and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro® is being readied for first approval in the US and AUS. The Company's other major focus is TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocelltd** 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.

[1] iData Research report focusing on European dental barrier membrane market. Data used to estimate incidence for other regions (US, Japanese and Australian) and cross checked with other local research reports and key opinion leader feedback.