CelGro® receives Australian market approval

- **Orthocell receives Australian market approval** to supply CelGro® in dental bone and tissue regeneration procedures
- **Validates the CelGro® platform technology** and positions Orthocell to achieve further approvals in nerve and tendon repair
- **Potential for Australian reimbursement by Q2 CY2021** which will assist with further technical and market validation for CelGro®
- **Positions Orthocell well for US FDA approval targeted for CY2021**

Perth, Australia; 23 December 2020: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce Australian market approval for its CelGro® collagen medical device, for introduction into the Australian dental bone and tissue regeneration market.

Orthocell Managing Director Paul Anderson, said: "Gaining Australian approval is a significant inflection point for our Company. This validates the CelGro® platform technology with a respected regulator and positions us well to achieve further approvals for the manufacture and supply of CelGro® in nerve and tendon repair – key growth areas for our business, responding to significant unmet need. I am excited by this strategic milestone and the positive step it represents on our continued pathway to making a meaningful impact in the US market."

Inclusion of CelGro® Dental in the Australian Register of Therapeutic Goods (ARTG) follows the recent announcement on 17th December 2020 confirming the TGA completed its review of the Company's regulatory application and that Orthocell successfully demonstrated compliance with the requirements of the Medical Device Regulations (Conformity Assessment) with respect to the safety and performance of CelGro® in dental bone and tissue regeneration procedures.

The Company is now focused on achieving reimbursement by insurers and has progressed its application to the Prostheses List Advisory Committee for inclusion on the Prostheses List ("PL"). Inclusion on the PL may be finalised by Q2 CY2021.

With EU and Australian market approval achieved and key opinion leaders (KOLs) actively engaging with the program, Orthocell is well positioned to gain the key US FDA approval which is targeted for CY2021 and to establish CelGro® as the best-in-class collagen membrane. Use of the product in Australia and the EU will assist with further technical and market validation for CelGro® as the US FDA approval approaches.

The Company believes CelGro®, manufactured by Orthocell in Western Australia, represents a breakthrough in bone and tissue reconstruction and is an area of significant clinical interest to the dental community. Clinical studies and post market feedback have demonstrated that CelGro® provides distinct advantages to assist surgeons deliver improved patient outcomes through superior

handling characteristics, tissue integration qualities and higher bone quality compared to the market leading dental membrane product.

Release authorised by Paul Anderson
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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®, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell recently received European regulatory approval (CE Mark) for CelGro®. The collagen medical device can now be marketed and sold within the European Union for a range of dental bone and soft tissue regeneration procedures and is being readied for first approval in the US and AUS. The Company's other major products are the 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 **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd