CelGro® Bone Regeneration in Dental and Orthopedic Applications

- CelGro® guided bone regeneration positive pre-clinical and clinical results published in the highly regarded journal ‘Tissue Engineering’
- Results demonstrate use of CelGro® enhances repair of critical bone defects and validates use of CelGro® in oral and maxillofacial reconstructive surgery and orthopedic applications
- Accelerated repair of critical bone defects represents an area of significant clinical interest to the dental and orthopedic community
- CelGro® is approved for use in the EU for dental and soft tissue reconstruction applications and currently under review for approval by the US FDA and the Australian Therapeutic Goods Administration

Perth, Australia; 17th September 2020: Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to announce publication of positive pre-clinical and clinical results for the use of CelGro® in enhancing repair of critical bone defects in the highly regarded “Tissue Engineering” Journal. The paper is entitled “Collagen Membrane for Guided Bone Regeneration in Dental and Orthopedic Applications”. A copy of the publication can be found CelGro GBR Publication.

This publication, in conjunction with previous pre-clinical studies published in Biomaterials (Announced 4th October, 2018), demonstrating CelGro® dosed with bone growth factors significantly improved the healing of cortical bone, validates that CelGro® is an ideal membrane for Guided Bone Regeneration (“GBR”) not only in oral maxillofacial reconstructive surgery but also in orthopedic applications such as open tibial fractures and incidences of non-union fractures.

Orthocell Managing Director, Paul Anderson, said: “We are delighted with the publication of the positive pre-clinical and clinical results indicating CelGro® aids in accelerating the repair of difficult to treat critical bone defects. These are exciting results as they further demonstrate the potential to extend the applications of CelGro® representing an area of significant clinical interest to the maxillofacial and orthopaedic community.”

CelGro® dental bone regeneration study results published in Tissue Engineering

In May 2018, Orthocell announced the results of a clinical study designed to evaluate the performance of CelGro® in dental GBR treatment. Dental GBR is a standard procedure used routinely in clinical practice, to preserve and restore bone volume to facilitate the subsequent placement of dental implants.

The clinical study involved a two-stage dental implant procedure with GBR in 10 patients (involving 16 dental implants). Bone defects were covered with the CelGro® collagen membrane after bone void filling. Various assessments related to performance of the CelGro® collagen membrane were evaluated up to 6 months post GBR treatment. Top line data indicated that use of CelGro® resulted in successful bone regeneration within 4 to 6 months of the procedure, enabling the next stage of implant surgery (placement of the crown). Further, the void-filling material was fully integrated into the newly regenerated bone, with no reported complications or adverse events.

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Lead author and chief investigator Dr Brent Allan commented: “My experience in using CelGro® in dental implant procedures has given me the confidence to use it in more complex Orthognathic procedures. These surgeries are life changing and technically demanding. Predictable and high quality bone regeneration is of upmost importance to deliver functional, as well as aesthetically pleasing outcomes for patients.”

Pre-clinical study results published in Tissue Engineering
The pre-clinical study also reported in this publication was conducted in a large animal model designed to assess the effectiveness of CelGro® to enhance the repair of cortical bone defects, when used in conjunction with autograft bone. The study was performed on 28 skeletally mature white rabbits. The animals were randomly assigned to one of five treatment groups: no treatment, defect only, autograft only, autograft plus competitor product Bio-Gide®, and autograft plus CelGro®.

CelGro® showed superior cortical bone alignment and reduced porosity at the defect interface, when compared to current market leading GBR product Bio-Gide®. Micro-CT evaluation showed early bridging over the defect area 30 days post-operatively, and nearly complete restoration of mature cortical bone at the bone defect site 60 days post-operatively. Histological analysis at day 60 after surgery, further confirmed CelGro® supported the regeneration of higher-quality bone, having a similar thickness and density to normal cortical bone. In addition, use of CelGro® in combination with autograft bone, resulted in significantly increased bone formation at the defect - compared to repair without the use of autograft bone.

Significance of CelGro® bone defect repair results
Positive oral and cortical bone defect repair results using CelGro® in conjunction with bone grafting material published in the highly regarded journal ‘Tissue Engineering’ provides further validation of the development plan for CelGro® starting in dental applications, and extending the concept of GBR into critical bone repair within orthopaedic applications.

GBR which is commonly used in maxillofacial dental surgery to restore bone volume, has been under-utilized in the repair of cortical bone defects in orthopaedics. GBR in orthopaedics appears to have been limited by the lack of an ideal scaffold that provides sufficient mechanical support to bridge the cortical bone whilst providing a favorable environment to promote the rapid repair and regeneration of high quality bone. Enhancing the rate of repair of the load bearing cortical bone, therefore, could enable patients suffering from serious fractures to return to pre-injury daily activities more rapidly.

Next Steps
Orthocell intends to leverage CelGro®’s ability to guide superior quality bone formation to further position CelGro® as the best-in-class collagen membrane for bone and soft tissue repair. The performance studies underpins the compatibility and versatility of CelGro® as a platform technology and highlights the potential to extend Orthocell’s innovative product range into orthopedic bone regeneration.
CelGro® is approved for use in the EU for GBR and soft tissue reconstruction and is currently under review for approval by the US FDA and the Australian Therapeutic Goods Administration (TGA).

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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® 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 @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.