ortho·cell
advancing tissue repair & regeneration

Orthocell Submits US Regulatory Application for CelGro®

- Orthocell submits 510(k) application for FDA regulatory clearance of CelGro® in the US
- Assessment of CelGro® European (CE Mark) application in final stages
- Commercialization of CelGro® in tissue support and bone applications can commence post European marketing authorisation and FDA clearance

Perth, Australia; 08 February 2017: Regenerative medicine company Orthocell Limited ("the Company") is pleased to announce it has submitted a 510(k) application to achieve FDA clearance of CelGro® collagen medical device, for introduction into the substantial US commercial market.

Orthocell's application for FDA clearance of CelGro® in the US follows its recent application for approval in Europe (CE Mark). Assessment of the CE Mark application is in its final stages. Both regulatory applications position CelGro® to be used as a tissue support and barrier membrane in various dental guided bone and tissue regeneration procedures.

Mr Paul Anderson said, "This is a very important milestone for the Company as we continue to commercialise our collagen medical device platform and prepare for entry to the world's largest markets in Europe and the US. With our active clinical programs for CelGro®, strong pipeline and accredited GMP facility, Orthocell is well positioned to take advantage of the opportunities that lie ahead."

OCC estimates the current US market for dental barrier membranes used in conjunction with bone graft substitutes is approximately 600,000 – 800,000 units per year, with a total value of the addressable US market of $240 - $320 million. The Company believes the introduction of CelGro® into the US commercial markets will benefit from the product's distinct advantages and the existing reimbursement environment which covers applicable dental surgical procedures and resorbable barrier membrane materials.

CelGro® is a biological medical device used as a barrier membrane in various dental procedures and as a scaffold for a variety of orthopaedic and general reconstructive surgical applications. Orthocell is undertaking a wide range of clinical studies using CelGro® to augment tendon, nerve and cartilage repair as well as to guide and promote bone regeneration.

CelGro® has a number of advantages over existing collagen scaffolds because it is strong, cell friendly, DNA free and can be manufactured in a range of thicknesses and sizes for use in many different surgical and dental applications. With its Australian sourced and manufactured pedigree, strong demand for the product is expected following launch.

Ph: +61 8 9360 2888 Fax: +61 8 9360 2899 www.orthocell.com.au

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For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited, Managing Director

P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Investor and Media enquiries

Ben Walsh
WE Buchan

P: + 61 411 520 012
E: bwalsh@buchanwe.com.au

About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for a variety of tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-approved stem cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. The Company's other major product is Celgro®, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications and is being readied for first regulatory approvals.