ortho·cell
advancing tissue repair & regeneration

Ortho-ACI® included on the Australian Register of Therapeutic Goods

- TGA has approved Ortho-ACI® for inclusion on the Australian Register of Therapeutic Goods (ARTG)
- Ortho-ACI® is the only ARTG approved intervention to repair damaged or degenerate cartilage in the knee or ankle joint without damage to the subchondral bone
- Approval and inclusion represents important milestone in the pathway to Australian reimbursement

Perth, Australia; 30 May 2017: Regenerative medicine company Orthocell Limited ("Orthocell or Company") is pleased to announce it has received confirmation from the Therapeutic Goods Administration (TGA) that Ortho-ACI® has been included on the Australian Register of Therapeutic Goods (ARTG).

Orthocell's Autologous Chondrocyte Implantation (Ortho-ACI®) for cartilage repair and regeneration has previously been approved for sale in Australia pursuant to a TGA issued manufacturing license, but in order to maintain regulatory approval in Australia for the commercial sale of Ortho-ACI® pursuant to the relevant transitional provisions, Orthocell had lodged an application for approval and inclusion on the ARTG.

Inclusion on the ARTG marks a significant milestone for the Company enabling the commencement of the process for reimbursement and also the wider sale and distribution of Ortho-ACI® for cartilage repair and regeneration within Australia and the treatment of patients in other countries such as Hong Kong, Singapore and New Zealand. This milestone also represents the first cell therapy for cartilage repair to be included on the ARTG.

Ortho-ACI® is the gold standard intervention for symptomatic defects of the articulating cartilage of the joints, predominately the knee and ankle. Damage to articular cartilage can occur through injury or normal wear and tear. When articular cartilage is damaged, it does not repair itself effectively like other tissues and cartilage defects lead to increasing joint pain and impaired mobility, which affects activities of daily living and exercise. These defects present a difficult clinical problem and if left untreated can lead to osteoarthritis.

Ortho-ACI® provides the opportunity for the body to regenerate its own cartilage and provide a functional and durable outcome. Orthocell has treated patients in Australia, Hong Kong and Singapore. Ortho-ACI® is indicated as a pre-arthritis cell therapy that is designed to treat the localized defects in the knee, patella and ankle that can lead to osteoarthritis and cartilage degeneration

Orthocell Managing Director Paul Anderson said "the inclusion by the TGA of Ortho-ACI® on the ARTG is a significant milestone for the Company and enables the continued pathway towards reimbursement."

For more information, please contact:

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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 tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-licensed 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.

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**