Initial results positive for CelGro® in human nerve regeneration

- Orthocell reports positive safety and tolerability results from interim review of clinical study using CelGro® for the repair of damaged or severed nerves
- Study designed to show CelGro® can be used to guide and promote nerve regeneration in damaged peripheral nerves of the hand and upper limb
- Performed in collaboration with a leading Australian orthopaedic nerve specialist and the St John of God Hospital Group Subiaco, Perth

Perth, Australia; 22 February 2017: Regenerative medicine company Orthocell is pleased to announce positive initial safety and tolerability results for its CelGro® collagen-based medical device, in a clinical study examining its use to augment the repair of nerve damage.

The first two patients treated in this pivotal trial had previously suffered traumatic peripheral nerve injury resulting in the inability to bend their elbow and significantly impacting basic activities of daily living. An interim review at 20 days post operation for the first two patients to receive CelGro® nerve regeneration treatment demonstrated that CelGro® is safe and was well tolerated with no inflammatory reactions or complications.

Orthocell Managing Director Paul Anderson said: "This initial assessment is very positive and represents an important step forward in the development of CelGro® in the very important area of human nerve regeneration. CelGro® allows for suture-less reconnection of the damaged nerve while guiding nerve regeneration and accelerating the healing process."

Peripheral nerve injury is most commonly caused by accidents or other trauma and in the US alone, over 20 million people are affected each year, at a cost of approximately $150 billion in annual health care dollars.

CelGro® is a biological medical device used in 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.

Orthocell has submitted CelGro® for first regulatory approval in Europe and expects to receive notice of approval of its CE Mark application in Q1 2017. Orthocell has also submitted a 510(k) application for FDA regulatory clearance of CelGro® in the US.

Receipt of these approvals will enable commercialisation of CelGro® products to commence in Europe and US, as well as trigger applications for other regulatory approvals in Australia and Japan in 2017.

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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-licensed 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.