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Orthocell secures new patent for suture-less repair of soft tissue

- Australian patent granted for CelGro® soft tissue reconstruction platform, which covers the method of suture-less repair of soft tissue defects
- Suture-free repair of soft tissue has potential to greatly improve the efficiency and efficacy of surgical procedures such as tendon, ligament and nerve repair
- CelGro® represents a breakthrough in soft tissue reconstruction and offers significant global commercial potential in soft tissue and bone repair

Perth, Australia; 18 January 2018: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has been granted a further Australian patent for its CelGro® collagen medical device platform for soft tissue regeneration and repair applications. The patent entitled "**Suture-less repair of soft tissue**" provides additional important intellectual property to protect the CelGro® product platform.

Orthocell Managing Director Paul Anderson said: "This is an important addition to our current global IP portfolio. Not only does it further strengthen our IP position in regenerative medicine products and surgical techniques for soft tissue repair, but it also acts to validate CelGro® as a collagen medical device platform, for use across multiple indications including bone, tendons, peripheral nerves and aid in the repair of spinal cord injuries. This comes at a perfect time for the company as we move our products through the registration processes in the US."

The patent has an expiry date of 12 October 2035. This is the first patent granted in the suture-less repair of tissue patent family. Further patent applications are in progress in all major jurisdictions including US, EU and Japan.

Suture-less repair of soft tissue refers to the method of repairing damaged soft tissue without the use of stiches. Suture-less repair has the potential to greatly improve the efficiency and efficacy of surgical procedures by simplifying techniques, reducing surgery time and reduces the risk of additional trauma to soft tissue through the use or sutures. Therefore, Orthocell's patented method of suture-less repair provides surgeons with an alternative to direct suture repair of soft tissue defects within tendons, ligaments and nerves.

For example, In the US alone, over 20 million people suffer from peripheral nerve injury as a result of motor vehicle, sporting or work related incidents every year, at an annual cost of approximately US$150 billion. Many of these injuries require surgical nerve reconstruction involving the use of collagen conduits that are secured in place using sutures. To address the disadvantages of suturing, Orthocell developed the CelGro® collagen medical device platform with handling characteristics to assist surgeons in performing complex reconstructive surgical procedures and enabling the suture-less repair of soft tissue defects.

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CelGro®'s nerve addressable market is estimated to be worth more than US$1.1 billion per annum, with approximately 700,000 procedures that could utilise CelGro® completed each year. Market growth is expected to be underpinned by the surgeons' preference for quality and functional bio-absorbable membranes. The company believes CelGro® represents a breakthrough in soft tissue reconstruction and offers significant global commercial potential in its existing addressable markets of bone, tendon, nerve and cartilage as well as much wider applications in general surgical and soft tissue reconstructive applications.

About CelGro®

CelGro® is a collagen medical device platform for soft tissue regeneration and repair applications manufactured by Orthocell at its quality controlled Good Manufacturing Practices (GMP) licensed facility in WA.

Orthocell has received market authorisation (CE Mark) of CelGro® collagen scaffold medical device in the EU for dental bone and soft tissue applications. The CE Mark allows CelGro® to be sold within EU countries, validates CelGro®'s quality manufacturing and product performance, and provides a strong foundation for indication expansion and regulatory approvals.

CelGro® has been shown to improve tissue in-growth and repair in clinical studies using the collagen medical device to augment repair of the rotator cuff tendon within the shoulder, to guide bone regeneration within the jaw and to assist in the rejoining of severed, or damaged peripheral nerves. CelGro® is a customisable collagen medical device with numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue in growth and repair.

Medical scaffolds are analogous to construction scaffolds in that they provide integral support to the soft tissue whilst it undergoes repair.

Example of suture-less repair of soft tissue

e.g. Peripheral nerve repair procedure

1. Peripheral Nerve Injury
Nerve severed and ends retracted into wound after traumatic injury to limb

2. Preparation of Repair Site
Nerve ends located and brought to repair site without tension

3. Microsurgical Repair with CelGro®
CelGro® secured around nerve ends, forming a sealed conduit

4. Nerve Healing
Conduit protects nerve ends and enhances regeneration

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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 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. 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.

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