advancing tissue repair & regeneration

FDA publication supports regenerative medicine acceleration

- FDA acknowledges the great promise of regenerative medicine and provides an updated view on balancing safety and innovation in this field
- Orthocell is well positioned to benefit from the FDA's revised approach given our advanced products that already demonstrate clinical safety and benefits to patients
- Orthocell is currently finalising a pre-IND submission to the FDA for Ortho-ATI®

Perth, Australia; 15 March 2018: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to highlight a new article from the FDA Commissioner in The New England Journal of Medicine, outlining the transformative promise of regenerative medicine and the need to adopt new procedures to advance these therapies more quickly towards FDA approval. This article follows on from the US Food and Drug Administration (FDA) comprehensive regenerative medicine policy framework released in November 2017.

Orthocell Managing Director Paul Anderson said: "We are pleased to see that the FDA is changing their approach to accelerate the approval and commercialization of regenerative medicine products. Orthocell's product portfolio is well positioned to benefit from the FDA's revised approach given our data clearly demonstrates clinical safety and benefits to patients, which provides the potential for Orthocell's innovative treatments to progress through the regulatory assessment as efficiently as possible."

The article was published by Dr. Scott Gottlieb, FDA Commissioner, and Dr. Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research and reiterates the FDA's commitment to ensure that the regulatory approval process for regenerative medicine products is as efficient as possible, while maintaining measures that ensure a high level of safety and efficacy.

Dr. Gottlieb and Dr. Marks wrote: "Working within the existing regulatory framework, the FDA will make use of all available regulatory pathways and will adopt the use of some new principles that we believe will make the appropriate premarket evaluation of stem-cell-based therapies more efficient."

As part of the FDA's ongoing efforts in regenerative medicine, the FDA have encouraged parties involved in innovative product development to engage early with the FDA during the research and development process. This can be achieved through scheduling informational meetings with the FDA, before more formal discussions are held as part of the process for an investigational new drug (IND) application. As such, Orthocell is leveraging the early engagement process and is currently finalising a pre-IND submission for Ortho-ATI®.

Read the full article in the The New England Journal of Medicine here:
http://www.nejm.org/doi/full/10.1056/NEJMsr1715626

For more information, please contact:

General enquiries	Investor enquiries	Media enquiries
Paul Anderson	**Joel Seah**	**Haley Price**
Orthocell Limited	**Vesparum Capital**	**Hales^2 Communications**
Managing Director		
P: +61 8 9360 2888	P: +61 3 8582 4800	P: +61 423 139 163
E: paulanderson@orthocell.com.au	E: orthocell@vesparum.com	E: haley@h-squared.com.au

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