

Orthocell Ltd

12:20 14 Jan 2021

Orthocell soars on receiving FDA clearance to supply CelGro product in US market

Orthocell Ltd (ASX:OCC) has received Food and Drug Administration's (FDA) 510(k) clearance to market and supply its CelGro collagen medical device for dental bone and tissue regeneration procedures in the US.

The company has registered Striate+ as the new global brand for the CelGro dental bone and tissue regeneration product and the company will market the procedure in the US under this brand.

Shares surge

Investors have responded positively with shares as much as 40% higher to 64.5 cents this morning, a new 12-month high.

This 510(k) clearance follows the company's application submitted to the FDA in May 2020.

The FDA determined that Orthocell's Striate+ is substantially equivalent to a predicate device and that it can, therefore, market Striate+ in the US.

"Significant inflection point"

Orthocell managing director Paul Anderson said: "The US approval has come sooner than expected and is a significant inflection point for our company.

"I am excited by this strategic milestone and the positive step it represents on our pathway to partnering Striate+ in dental GBR indications.

"I look forward to working with our leading dental surgeons to introduce the new global brand, Striate+, previously branded as CelGro® Dental, and to make a meaningful impact in the US market."

Validates technology

Striate+ has been approved for supply in dental bone and tissue regeneration procedures such as dental bone defect repair, augmentation around dental implants in immediate and delayed extraction sockets and guided tissue regeneration procedures in intrabony periodontal defects.

US market clearance of Striate+ validates the SMRT™ manufacturing technology and provides a pathway for Orthocell to continue driving the development of CelGro collagen medical device in the key peripheral nerve repair application.

The global peripheral nerve repair market is estimated to be worth more than US\$7.5 billion per annum, with around 3 million procedures that could use the nerve repair product each year.

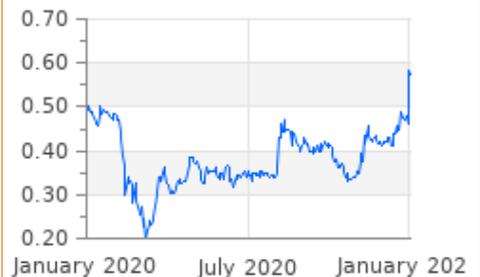
Next steps

The company will now pursue negotiations with multi-national dental companies for US marketing and distribution

Price: 0.575

Market Cap: \$106.6 m

1 Year Share Price Graph



Share Information

Code: OCC

Listing: ASX

52 week High Low
0.645 0.18

Sector: Pharma & Biotech

Website: www.orthocell.com.au

Company Synopsis:

Orthocell Ltd (ASX:OCC) 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 CelGro®, a collagen medical device which facilitates tissue repair and healing.

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rights, with Orthocell to retain manufacturing of the finished product.

With the US, EU and Australian market approval achieved and key opinion leaders (KOLs) actively engaging with the program, Orthocell is well-positioned to secure a distribution partner and establish Striate+ as the best-in-class dental resorbable collagen membrane.

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