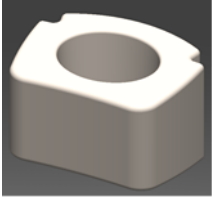


ASX Media Release



## **Allegra confirms route to FDA approval following successful pilot animal study**

**Sr-HT-Gahnite Spinal Cage Device**

SYDNEY 6 April 2021– Allegra Orthopaedics Limited (Allegra) (ASX: AMT) provides the following update on its flagship innovation project, the Sr-HT-Gahnite Spinal Cage Device (Spinal Cage):

Further to Allegra’s ASX announcement of 21<sup>st</sup> December 2020, where the company advised the dynamic torsion, compression and shear tests had passed the regulatory-required 5 million cycles without any signs of fracture or failure, Allegra is now pleased to report the successful completion of the 8 week timeline for the large animal pilot study performed at SAHMRI (South Australian Health and Medical Research Institute).

CT imaging taken at intervals throughout the study show stable implants with complete fusion in both lumbar and cervical zones, confirming the Spinal Cage performs as intended.

Allegra will now strive to reproduce these outcomes in a 6 month large animal trial in Australia, with the intention of obtaining approval from the Federal Drug Administration (‘FDA’) in the United States.

The results of the 8 week animal study mark a pivotal milestone and a **confirm a viable pathway to obtaining a 90 day FDA 510(k) clearance in the near future.**

In addition Allegra finalized its manufacturing process of the Spinal Cage and will now enter final validation and verification testing. The commencement of these tests and ultimately their completion represent some of the **final steps towards Allegra’s submission to Australia’s Therapeutic Goods Administration (‘TGA’) in November this year.**

Dr Nick Hartnell, as both Director and medical advisor to Allegra, commented that *“Demonstrating both fusion and stability of a Spinal Cage made of an alternative material to those currently available in the market such as metal or peek is an exciting milestone. It also demonstrates just one of a multitude of applications for the Sr-HT-Gahnite technology. I look forward to seeing the positive results from the pilot study duplicated in the large animal study over the next 6 months and the subsequent applications to the TGA and FDA.”*

Allegra Orthopaedics is the sole proprietor of the Sr-HT-Gahnite material and aims to apply the technology to fulfilling unmet needs across a broad range of applications including both Spine, Hip & Knee and extremities.

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**ABOUT ALLEGRA ORTHOPAEDICS:**

We aim to help bring the freedom and happiness of pain-free movement to people's lives. We achieve this through providing the best possible solutions for patients, from world-wide industry leading orthopaedic products through to Australian innovations. Allegra's principal product, the Active Total Knee, has significantly improved the quality of life for many people and remains a focused product line. Allegra is also the exclusive distributors of Waldemar Link GmbH & Co. KG products in Australia. Link consists of a range of complex lower limb, hip and knee replacements, including oncology solutions. The Link products add to Allegra's well-developed range of products for distribution from international suppliers covering all specialties from foot and ankle to upper limb. The company is pleased to continue to build upon its extensive portfolio of patents. It has strong research relationships with universities, companies and surgeon inventors.

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