

ASX Media Release

Allegra reaches significant milestone for

Sr-HT-Gahnite Spinal Cage Device



SYDNEY 15 November 2019– Allegra Orthopaedics Limited (Allegra) (ASX: AMT) provides the following update:

A significant milestone has been reached with the commencement of the preclinical large animal study, approved by the FDA for the biodegradable cervical fusion device. The study is taking place in Lyon France and being undertaken by a Board certified Australian orthopaedic spinal surgeon.

The study will follow the Good laboratory practice (GLP) principles intended to assure the quality and integrity of non-clinical laboratory studies. The purpose of this nonclinical GLP study is to evaluate the safety, efficacy and performance of the device in the sheep model, closely translatable to the human spine. The study will also demonstrate the load bearing capability of the Sr-HT-Gahnite spinal fusion cage.

The animals will be evaluated at 3, 6 and 12 month time points, representing early, mid and long-term implantation. Fusion is expected to occur by 6 months and full degradation is not expected prior to years 4-5. All animal breeding and experiments will conform to Australian code, European Directive 2010/63/EU and the French regulation on the protection of animals used for scientific purposes.

The success of this study at the 6 month time point will lead to a small confirmatory human clinical trial in Australia, the final step before commercialisation.

Jenny Swain, Chief Executive Officer, commented that "We are extremely excited to start the large animal study in line with FDA requirements. Allegra have successfully reached a significant stage in the commercialization of our bio-ceramic material. The project is gaining momentum, leading us into the next chapter of human clinical trials being undertaken in Australia." Contact details:

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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, including its global licensee to the composite biocompatible ceramic material known as Sr-HT-Gahnite from the University of Sydney.