



ASX Media Release
Large Animal Study Completed Showing
Positive Results
For Sr-HT-Gahnite Spinal Cage
Device

SYDNEY 22nd February 2023 – Allegra Orthopaedics Limited (**Allegra**) (ASX: AMT) today announces positive results upon completion of the large animal sheep study performed at South Australian Health and Medical Research Institute – Preclinical, Imaging and Research Laboratories (SAHMRI – PIRL) for its flagship innovation project, the Sr-HT-Gahnite Spinal Cage Device (Spinal Cage).

The primary endpoint was achieved with no safety concerns observed. The positive findings demonstrated safety and performance outcomes equivalent to an FDA-cleared product. The animals were evaluated at 13 and 26-week endpoints.

The results achieved the study acceptance criteria:

- (1) The bone healing response demonstrated that the Spinal Cage achieved bone growth indicative of a fused spinal level
- (2) The Spinal Cage induced no local tissue response, therefore demonstrating biocompatibility
- (3) The Spinal Cage induced no adverse effects on the animals.

During the study, there were no significant differences in the sheep blood or organ analyses between the Spinal Cage and the FDA-cleared control device. These results indicate that the Spinal Cage did not induce adverse toxicity outcomes. The results demonstrated bone fusion between the vertebrae, which progressed between 13 weeks and 26 weeks, with no evidence of local inflammation or tissue damage.

To support and stabilise the implant and vertebrae, fixation plates and screws were used in this study, as per standard practice in spinal fusion procedures. Due to the anatomical differences between the sheep and human spines, contact of the cages with plates and screws was observed in some cases, resulting in minor chipping. This contact and resulting chipping are not anticipated to occur in humans, where the design of the plate and screws is intended for human use. However, even when minor chipping was observed, it did not impact the bone growth, fusion, or integrity of the Spinal Cage.

Dr Chris Christou BVSc PhD, study veterinary surgeon and SAHMRI-PIRL Director, commented that *“the large animal study results demonstrate that the Sr-HT-Gahnite Spinal Cage achieved spinal fusion, with bone healing rates equivalent to the control device. No evidence of toxicity or local inflammation was observed”*.

The completion of this study and the positive results are important steps to support Allegra’s FDA 510(k) submission in the USA, which remains on track to be submitted end of March 2023.

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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 Spine, Hip & Knee, and extremities.

This announcement has been authorised for release by Jenny Swain, CEO.

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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 distributor 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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