

ASX Media Release

Milestone Achieved Sr-HT-Gahnite Systemic Safety Evidence

SYDNEY 14th March 2022– Allegra Orthopaedics Limited (Allegra) (ASX: AMT) is pleased to announce the first published article demonstrating the systemic safety of the material, Sr-HT-Gahnite, under good laboratory practice (GLP) conditions.

Along with device performance and local safety, systemic safety is one of the three major aspects of the device that must be evaluated in a large animal for regulatory approval – demonstrating that the presence of the device does not have any adverse effects to the patient’s distant tissues or body systems holistically.

Pleasingly, the results of this study demonstrate the systemic safety of the Sr-HT-Gahnite Cervical Fusion Cage, following implantation of the spinal cage in the sheep model. There were NO major changes in blood haematology or biochemistry parameters observed, NO systemic distribution of strontium to the blood and wool, and NO macroscopic or histopathological abnormalities in the distant organs when Sr-HT-Gahnite was implanted, compared to baseline and control values.

Importantly, this study also addresses any questions from The Food and Drug Administration (FDA) regarding the presence of strontium – due to safety issues with past medical devices and pharmaceutical products that contain strontium, FDA requires a high level of assurance that strontium in the device does not present a safety risk to the patient.

These positive results instill further confidence that Allegra is on track to obtain a 90 day FDA 510(k) clearance for the United States in the next 12 months.

The full results have been published in the peer-reviewed Acta Biomaterialia journal. The article titled “Design and evaluation of 3D-printed Sr-HT-Gahnite bioceramic for FDA regulatory submission: A Good Laboratory Practice sheep study”, is authored by Allegra engineer Ellen Newsom, with corresponding author Professor Hala Zreiqat, further strengthening the research collaboration between Allegra and The University of Sydney.

A comment taken from the abstract of the article is as follows;

“This paper is considered original and innovative as it is the first that thoroughly reports the systemic biological safety of previously undescribed bioceramic material, Sr-HT-Gahnite. The study has been performed under good laboratory practice, in line with FDA requirements for assessment of a new interbody fusion device, making the results broadly applicable to the translation of sheep models to the human cervical spine; and also the translation of Sr-HT-Gahnite as a biomaterial for use in additional applications.”

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We expect this study to be of broad interest to the readership of Acta Biomaterialia. Its findings are directly applicable to researchers and clinicians working in bone repair and the development of synthetic biomaterials"

The published article can be accessed at the following address:

<https://www.sciencedirect.com/science/article/abs/pii/S1742706122000459?via%3Dihub>

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 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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