



ASX Media Release
AMT Submits 510(k) for Spinal Cage
FDA Clearance

SYDNEY 31st March 2023 – Allegra Orthopaedics Limited (**Allegra**) (ASX: AMT) today announces the submission of their 510(k) for the Sr-HT-Gahnite Spinal Cage Device (**Spinal Cage**) to the U.S. Food and Drug Administration (**FDA**).

Allegra's submission to the FDA has continued to be on track as per our previous communications. The FDA submission follows the completion of a range of studies where successful outcomes were achieved. The submission includes extensive laboratory and pre-clinical investigations, including the positive results from the recently completed large animal study with the South Australian Health and Medical Research Institute – Preclinical, Imaging and Research Laboratories (SAHMRI – PIRL) (Refer ASX announcement 22nd February 2023).

The studies demonstrated the product's mechanical strength, physical properties, safety, and efficacy in cervical fusion. Additionally, thorough sterilisation and biocompatibility evaluations have been performed providing further evidence of the device's biological safety and readiness for clinical settings.

Allegra has engaged with the FDA through pre-submission discussions to provide what we believe to be a comprehensive submission. Following submission, Allegra anticipates feedback from the FDA within a 90-calendar day review period. Subject to FDA approval, we look forward to bringing our 3D-printed bioceramic spinal fusion cage to market.

This milestone marks the culmination of over nine years of Allegra's innovation activities commencing in 2014. Regulatory submission for this flagship project is a significant step forward for Allegra and advanced ceramics in orthopaedics.

Jenny Swain, Allegra Chief Executive Officer, said: *"This submission could not have been achieved without our committed team of engineers diligently working on this project to achieve this crucial milestone. I would also like to gratefully acknowledge the universities, suppliers, and test facilities that provided support in generating the results supporting this submission."*

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.

Contact details:

Robyn Slaughter
Company Secretary
T: +61 2 8072 1435

Allegra Orthopaedics Limited

Level 8, 18 --- 20 Orion Rd, Lane Cove West NSW 2066 Australia; PO Box 72 St Leonards NSW 2065 Australia

T +612 9119 9200 **T** Toll Free 1800 644 370

F +612 9439 4441 **F** Toll Free 1800 624 223

E sales@allegraorthopaedics.com

www.allegraorthopaedics.com



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.

Allegra Orthopaedics Limited

Level 8, 18 --- 20 Orion Rd, Lane Cove West NSW 2066 Australia; PO Box 72 St Leonards NSW 2065 Australia

T +612 9119 9200 **T** Toll Free 1800 644 370

F +612 9439 4441 **F** Toll Free 1800 624 223

E sales@allegraorthopaedics.com

www.allegraorthopaedics.com