

ASX/Media Release

Allegra Targets USA Market

Meets with FDA

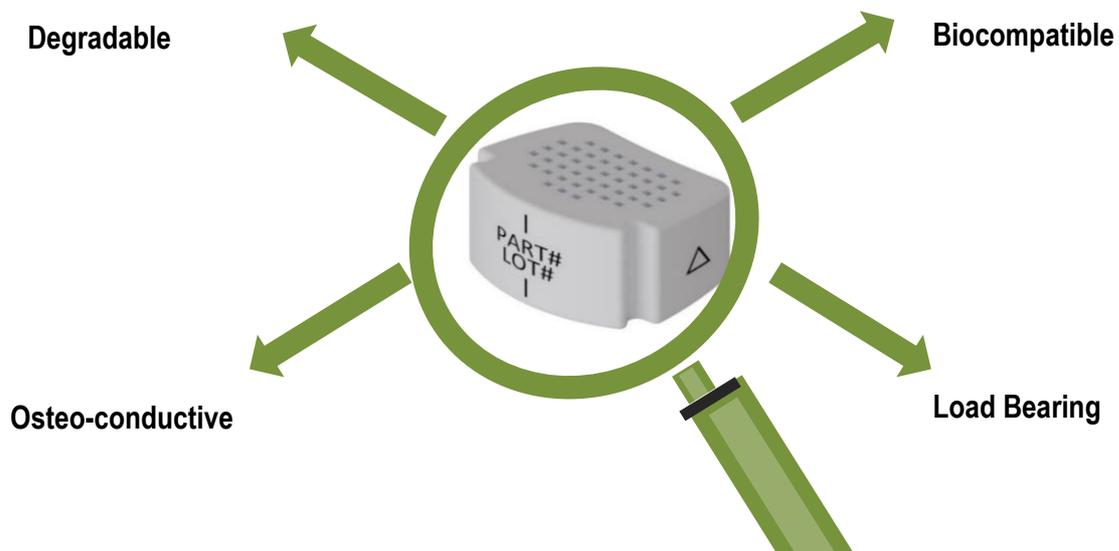
Sr-HT-Gahnite Spinal Cage Device

SYDNEY 21 November 2018– Allegra Orthopaedics Limited (Allegra) (ASX: AMT) provides the following update:

On the 7th November 2018 Allegra Orthopaedics Limited met with the USA’s Food and Drug Administration (FDA), in Washington DC, to discuss the approval process for release of the Sr HT–Gahnite spinal cage device into the USA.

Our Sr-HT Gahnite spinal fusion device works to regenerate bone under spinal load conditions and is completely resorbed by the body, leaving the body free of foreign materials. In addition to being the first degradable structural porous bioceramic available in a medical implant, our large animal study has shown the device can achieve spinal fusion, in the absence of added bone grafts, reducing operative time while addressing clinical limitation associated with existing spinal fusion devices, e.g. minimal bone integration and contribution to infection.

Unlike other similar FDA-approved devices, Allegra’s Sr HT–Gahnite spinal cage design does not need a large central cavity to hold bone graft. Rather, the design consists of a network of 3D-printed pores that allow bone growth.



The FDA indicated that a 6-12 month, large animal, study will be sufficient, in order to prove the success of this device without a large central hole.

Since this is the world's first load-bearing and degradable spinal cage device, the FDA will require a small human confirmatory study, to ensure the animal results are representative of clinical benefit in the human population. Furthermore, the FDA responded positively to this small human study taking place in Australia.

Jenny Swain, Chief Executive Officer, commented that *"This is a significant milestone for Allegra, as it clarifies our regulatory pathway into the US market. Allegra is planning the clinical trial in a way that will address FDA, EU and TGA regulatory requirements. This first meeting with the FDA was considered a great success. We are excited to start the animal study in line with FDA requirements and move into the human clinical trial. Conducting the trial in Australia allows Allegra to capitalise on local, established expertise and further develop our relationships with surgeon advisory groups."*

Allegra is committed to a strong R&D program that remains focused on developing additional key technologies related to Sr-HT-Gahnite

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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.

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