



PRESS RELEASE

SIRAKOSS Receives U.S. FDA 510(k) Clearance for Osteo³ ZP Putty to Catalyse Rapid and Complete Bone Regeneration

Combines Best-in-Class Bone Repair with Intraoperative Ease-of-Use for Spine and Trauma Bone Grafting Applications

Aberdeen, UK, 17 June 2020 – SIRAKOSS Ltd, a developer of nanosynthetic bone graft substitutes, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Osteo³ ZP Putty, its new nanosynthetic bone graft substitute. Osteo³ ZP Putty has been designed to provide surgeons with an easy-to-use, advanced solution for filling voids or gaps during spine and trauma bone grafting procedures.

“Osteo³ ZP Putty brings patented, best-in-class handling properties to enhance SIRAKOSS’ exceptional nanosynthetic bone regeneration potential, giving surgeons a one-two punch of repair confidence and intraoperative ease-of-use for spine and trauma bone grafting applications,” said Tom Buckland, Director of SIRAKOSS. “U.S. FDA clearance is obviously a major achievement for SIRAKOSS, enabling us to implement the commercial strategy for this game-changing product.”

Synthetic bone grafts are used to fuse bones together during surgery to correct congenital or degenerative conditions, such as curvature of the spine, or following a traumatic injury where the bone fails to heal. Osteo³ ZP Putty has a unique surface chemistry designed to catalyse rapid and complete bone regeneration following these procedures.

“Our Osteo³ ZP Putty has demonstrated excellent pre-clinical performance in models of spinal fusion and trauma repair,” explained Iain Gibson, co-founder and Director of R&D at SIRAKOSS and Professor of Acellular Regenerative Medicine at Aberdeen University. “Being able to provide surgeons with the synthetic bone graft in a pre-packed syringe, saves time and is far easier to handle during the procedure in the operating room environment. This product was developed with grant funding support from Innovate UK, part of the United Kingdom Research and Innovation (UKRI) organisation, and we’d like to thank them for their continued support in the development of this more advanced, next generation product.”

About Osteo³ ZP Putty

Osteo³ ZP Putty is an entirely synthetic, nanoporous bone graft substitute composed of novel inorganic granules suspended in a fully-synthetic resorbable carrier. The putty has been designed to catalyse rapid and complete bone regeneration and can be used immediately, directly from the pack. This brings important benefits to patients, who will need less time under anaesthetic, and implies savings in

theatre time and cost. Successful early pre-clinical studies support the potential for reliably achieving rapid patient recovery. Osteo³ZP Putty also allows clear imaging of postoperative repair and is readily resorbed once integrated with host tissue.

About SIRAKOSS

SIRAKOSS is developing nanosynthetic graft substitutes to facilitate complete bone repair and transform patient healing. The SIRAKOSS bone graft substitutes utilise advanced and proprietary understanding of nanostructures and nanochemistry to catalyze faster bone regeneration coupled with total graft resorption. SIRAKOSS was spun out of the University of Aberdeen in 2011 based on the research of Professor Iain Gibson and is supported through financing from Epidarex Capital and Scottish Investment Bank, the investment arm of Scottish Enterprise together with grant funding from Innovate UK. For more information visit www.sirakoss.com.

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