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Artoss, Inc. Recruits 100 Patients in Multicenter Clinical Study on NanoBone® Bone Graft in Foot and Ankle Surgery

Early ARK Study Experience Provides Supporting Data for NanoBone Standalone Performance

St. Cloud, MN, June 7, 2021 / -- Artoss, Inc. (St. Cloud, MN), exclusive North American distributor for NanoBone for orthopaedic indications, announced the enrollment of the first 100 patients in the Artoss Prospective Foot and Ankle Registry Outcomes (ARK) Study. With over 100 patients recruited to-date, ARK is already exceeding its recruitment objectives.

ARK is a prospective observational study to view how NanoBone Bone Graft Substitute products, SBX Putty and QD, perform in foot and ankle surgery. The primary objective of ARK is to document and analyze NanoBone SBX Putty and QD use in foot and ankle surgery as a standalone bone graft, or in combination with local bone only (but not with any other products) and determine both radiographic and clinical outcomes successes. Relevant patient outcomes being tracked include radiographic measures such as fusion outcome and instrumentation integrity. Clinical outcomes include symptom and function improvement measurements, such as Foot and Ankle Ability Measure (FAAM) and Visual Analog Scale (VAS) scores.

James J. Cassidy, Ph.D., Chief Operating Officer and President of Artoss, Inc., announced, “By achieving this major milestone, we want to express our gratitude to our foot and ankle surgeon investigators and research coordinators who support us in achieving our goals for ARK. Their diligent investigation of NanoBone as a standalone product demonstrates NanoBone’s value in foot and ankle surgery. The early outcomes we are seeing in ARK and in commercial use in the U.S. is supporting the rapid adoption of NanoBone as the best standalone synthetic bone graft on the U.S. market.”

“NanoBone is performing exceptionally well in the ARK Study to-date,” said Dr. David Yeager, podiatric surgeon in Morrison, Illinois. “The putty-like tactile consistency ensures it stays where you put it and it’s ready out-of-the-box with no preparation required. Couple that with the rapid healing response, and NanoBone is in a standalone class of its own. NanoBone allows me greater flexibility in approaching each case and focusing on what’s best for my patients. My early follow-up with my NanoBone patients shows that rapid osteogenesis can be expected from NanoBone Bone Graft Substitute.”

NanoBone has consistent outcomes in bone grafting in multiple orthopaedic indications. NanoBone achieves these outcomes with no preparation required, excellent handling for surgeons, and creation of an osteogenic matrix within 14 days. NanoBone exhibits clinical and radiographic healing in as little as 8 weeks.¹ The dramatic growth in NanoBone procedures further secures its market position as a leader in the bone repair space. There is growing acceptance by surgeons that not all bone graft substitutes are the same, given the rapid osteogenic matrix formation by NanoBone within 14 days of implantation. NanoBone formulation begins with actual nanometer size HA particles, rather than the nanometer surface area claimed by some competitive products.

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About NanoBone

NanoBone was first cleared by the Food and Drug Administration (FDA) in 2015 after having been successfully used in Europe for ten years. Clinical publications have identified bone graft substitutes as an increasingly important component of many orthopaedic procedures. Consistent healing in orthopaedic procedures is a significant unmet clinical need and one where NanoBone may provide an effective option.

NanoBone is a commercially available product in the U.S. intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty resorbs and is replaced with bone during the healing process. Artoss and NanoBone are trademarks of Artoss GmbH.

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About Artoss, Inc.

Artoss, Inc. (St. Cloud, MN) is a medical device company that is a leading distributor of bioidentical bone graft substitutes to treat multiple orthopaedic indications and is dedicated to the development of tools and products for effectively treating a variety of orthopaedic conditions requiring surgical intervention. The company markets, NanoBone Bone Graft, which gives clinical outcomes comparable to autograft with less postoperative pain and complications. Artoss, Inc. has an experienced management team with extensive experience in orthopaedic medical devices.

¹ Ortega, G. Using Nanotechnology as stand-alone bone grafting in open fracture bone defects and nonunions, Orthopaedic Trauma Association Annual Meeting, #1043, 2020.