NanoBone®
Rapid Osteogenesis

FOR IMMEDIATE RELEASE

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Artoss, Inc. Announces FDA Clearance of NanoBone® SBX Putty for Standalone Use in Posterolateral Spinal Fusion

Product release will boost NanoBone commercial efforts

St. Cloud, MN, April 24, 2019 / -- Artoss, Inc. (St. Cloud, MN), a medical device company that is pioneering the use of advanced bone graft substitutes to treat multiple orthopaedic indications, announced FDA Clearance of NanoBone® SBX Putty for Standalone Use in Posterolateral Spinal Fusion.

NanoBone was tested alone (without addition of autograft or bone marrow aspirate) in the ASTM International standardized animal model and found to be equivalent to the "gold standard" autograft in fusion rate.

James J. Cassidy, Ph.D., Managing Director of Artoss, Inc., the exclusive North American distributors for NanoBone in orthopaedic surgery, said, "The ASTM standard animal model for lumbar intertransverse process spinal fusion is a very challenging model designed to replicate clinically relevant fusion rates for iliac crest autograft in the posterolateral spine. A majority of bone void fillers must be mixed with autograft in order to achieve equivalent fusion rates to autograft alone. We're pleased to offer surgeons a synthetic alternative to autograft that does not require mixing with autograft or bone marrow. Using a synthetic bone void filler alone offers significant cost savings to hospitals. NanoBone stands alone."

"NanoBone Bone Graft used as a standalone in posterolateral spinal fusion represents a significant advancement in patient care." said J. Eric Gee, M.D., of Valdosta, Georgia. "Eliminating the need to mix synthetic graft with autograft or to harvest and concentrate bone marrow aspirate will save time and money as well as streamline operating room procedures."

Including spine, NanoBone has consistent and cost-effective outcomes in bone grafting in multiple orthopaedic indications. NanoBone achieves these outcomes with no preparation required, excellent handling for surgeons, creation of an osteogenic matrix within 14 days, and clinical and radiographic healing in as little as 8 weeks. The dramatic growth in NanoBone procedures further secures its growing 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 of NanoBone within 14 days.

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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.

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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 Substitute, which is 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.