

News Release

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BioSET Announces Initiation of Clinical Trials for AMPLEX Osteo-Promotive Bone Graft System for Spine Fusion

Pilot Studies Initiated in both the U.S. and Canada, and First Patient Treated

ROCKVILLE, Maryland – December, 2008 – BioSurface Engineering Technologies, Inc.[BioSET], a privately held company developing synthetic peptide growth factor mimetics for advanced tissue repair, reported today that two pilot clinical trials, one in the United States and one in Canada, have been initiated with the Company's AMPLEX osteo-promotive bone graft system. AMPLEX is a novel combination medical device that incorporates BioSET's B2A, a BMP-2 growth factor analog, with ultra high-grade ceramic bone scaffold for use in lumbar interbody spine fusion surgery.

BioSET has received approval from the U. S. Food and Drug Administration ("FDA") to initiate a pilot safety and preliminary efficacy study to evaluate its AMPLEX osteo-promotive bone graft system in approximately 22 patients. Additionally, the company received approval from Health Canada of a similar study design intended to enroll 24 patients in Canada. Each study is a randomized, prospective, multi-center, controlled study comparing autograft from the hip to AMPLEX in lumbar interbody fusion procedures for patients with degenerative disc disease.

BioSET also reports the first patient surgery in its Canadian study was performed by Dr. Stephan du Plessis, Assistant Professor, Neurosurgery and Vice Chairman, University of Calgary Spine Program at the Foothills Medical Centre in Calgary, Canada. Dr. du Plessis commented, "This patient presented with grade 1 spondy and foraminal stenosis at level L5/S1. We performed a decompression and standard TLIF in combination with posterior fixation for this patient using this new material as the bone graft. We found the material handled no differently than other ceramic graft alternatives when packing into the cage and the disc space. The patient is recovering well after surgery and I will be keenly interested in how this new growth factor material compares to other osteo-inductive synthetics."

“This first use of AMPLEX in our Canadian clinical series represents a significant achievement in our development of a safe and effective alternative to autologous graft harvested from a second surgical site as well as bone graft substitutes that are either very costly, have safety concerns or have not been proven to be osteo-inductive”, noted Tom Roueche, BioSET President and CEO. Further, Mr. Roueche indicated, “We look forward to enrolling our first patient in the US study later this month, and reviewing the top line data from all patients 6 month follow-up visits in the second half of 2009.”

BioSET also reported that the company received a Notice of Allowance of BioSET’s patent titled “Positive Modulator of Bone Morphogenic Protein 2” which covers the B2A peptide used in the AMPLEX graft construct. The patent, expected to publish early in 2009, is the first in a series of worldwide patent filings covering AMPLEX, its materials and methods of use. This seminal patent will provide US patent protection through the year 2029.

Additionally, BioSET reported publication of two preclinical studies relating to the safety and effectiveness of AMPLEX in spine fusion. The May 2008 issue of Spine described a study from researchers at the University of Iowa that AMPLEX enhanced spine fusion as compared to iliac crest autograft in a rabbit model. A 2008 presentation at the Orthopedic Research Society authored by researchers in Towson, MD demonstrated that AMPLEX enhanced spine fusion in a sheep interbody fusion model.

About *Bio*Surface Engineering Technologies, Inc.

BioSET is a private, clinical stage company developing proprietary therapeutic peptides as medical devices to improve bone and soft tissue repair. BioSET products incorporate chemically synthetic growth factor mimetics with procedure specific biomaterials to address multiple large and clinically relevant applications. The company’s lead program combines BioSET’s novel B2A osteo-promotive peptide with a resorbable bone scaffold to offer substantial safety and cost benefits to currently available bone grafting alternatives. For more information, please contact BioSET at: 301.795.6010