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Harvest Technologies to present at “3rd Annual Stem Cell Summit”
President Gary Tureski to review the scientific foundation leading to first
randomized, placebo-controlled clinical trial now underway in the US
using autologous adult stem cells to treat
patients with end-stage *Critical Limb Ischemia*

PLYMOUTH, Mass., Feb. 19, 2008—Harvest Technologies Corp. (www.harvesttech.com) announced today its President, Gary Tureski, will present at the 3rd Annual Stem Cell Summit, Hilton New York, on Tuesday, Feb. 26, 2008. The annual Stem Cell Summit brings together the leading industry, investment, practitioner, and research innovators within the rapidly expanding field of stem cells.

The Food and Drug Administration (FDA) recently granted Investigational Device Exemption (IDE) approval to Harvest Technologies to commence a 48-patient ‘feasibility’ clinical trial, now underway, using the company’s BMAC™ System to treat patients with **Critical Limb Ischemia (CLI)**. The BMAC System is a point-of-care device for concentrating a patient’s own (autologous) bone marrow stem cells in approximately 15 minutes. The study’s design provides for injecting these cells into the affected limb to reduce the potential for limb amputation. It is believed that the injection of stem cells will arrest and possibly reverse the effects of CLI, a late-stage form of **Peripheral Arterial Disease (PAD)**. Patients who are being enrolled in this study have exhausted all other surgical options and are at extreme risk for major amputation. This U.S. clinical study is being led by **Principal Investigator Mark D. Iafrati, M.D.**, Chief of Vascular Surgery at Tufts-New England Medical Center, Boston. Six additional major university-based medical centers also are participating in the clinical study.

“The scientific literature is rife with studies about the therapeutic potential of autologous adult stem cells derived from bone marrow. However, the major obstacles associated with autologous adult stem cell therapy have been the lack of a simple, practical method for integrating cell therapy within the clinical setting *and* credible scientific-based, randomized controlled studies,” said Gary Tureski, President of Harvest Technologies. “Our BMAC technology is making the benefit of cellular therapy available *right now* for European physicians. They are able to harvest *and concentrate* autologous adult stem cells easily and quickly, at the point of care—thereby enabling them to develop non-surgical approaches for treating orthopedic and vascular diseases, *today*.”

Berthold Amann, MD, a specialist in vascular medicine at the Berlin Vascular Center of Franziskus Hospital, recently completed a 60 patient end-stage (Fontaine IV Rutherford Grade III/Cat.5) CLI pilot study. All patients were injected with their own *concentrated* bone marrow stem cells. Of the 60 patients, 45 had been enrolled for more than six months. Of this group, **62% (28/45) avoided amputation, directly resulting from the stem cell therapy, according to Dr. Amann.** This is particularly impressive considering that 80% of these patients had already failed revascularization or had been scheduled for amputation. (The other 15 patients’ results will be reported after their six-month milestones are reached.) Equally important, Dr. Amann reported that concentrating bone marrow with the Harvest BMAC system is a highly efficient 15-minute bedside procedure requiring half the volume of aspirate of the *gold standard*, Ficoll separation. Because of the BMAC system’s separation efficiency and short processing time, this critically ill patient population required only local anesthesia, thus eliminating the risks associated with general anesthesia. With the BMAC System, Dr. Amann and other European clinicians are now able to offer stem cell therapies for vascular, cardiovascular and orthopedic diseases.

Until now, it has been difficult to process *and concentrate* a clinically significant dose of adult stem cells from a patient’s bone marrow at the point of care. The BMAC System is the world’s *first* technology that produces clinically significant amounts of stem and precursor cells from a small aspirate of autologous bone marrow in just 15 minutes. “Cells concentrated by the Harvest point-of-care device show similar or greater functional activity compared to Ficoll isolation. However, the greater yield of cells and wider variety range of cell types for the Harvest device translate into an even greater therapeutic effect.”¹

Harvest Technologies is a privately held company based in Plymouth, Mass.

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¹ “Concentration of Bone Marrow Total Nucleated Cells by a Point-of-Care Device Provides a High Yield and Preserves Their Functional Activity”, Heeschen et al, Cell Transplantation Vol 16 pp 1059-1069.