News Release

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Harvest Technologies announces FDA approval to begin the first randomized, placebo-controlled clinical trial in the United States using autologous adult stem cells to treat patients with end-stage *Critical Limb Ischemia*

PLYMOUTH, Mass., May 29, 2007—**Harvest Technologies Corp.** (www.harvesttech.com) announced today that the Food and Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval to commence a 48-patient 'feasibility' clinical trial 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 will be enrolled in this study have exhausted all other surgical options and are at extreme risk for major amputation.**

This U.S. clinical study will be led by **Principal Investigator Mark D. Iafrati, M.D.**, Chief of Vascular Surgery at Tufts-New England Medical Center, Boston. In the next month, five additional major university-based medical centers will be added to participate in the clinical study.

"I am hopeful that Harvest's BMAC technology will be a dramatic step forward in helping us treat CLI patients who otherwise would face eminent leg amputation," said Dr. Mark Iafrati.

"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*."

In a European pilot study conducted by Berthold Amann, MD, a specialist in vascular medicine at the Berlin (Germany) Vascular Center of Franziskus Hospital, 23 end-stage CLI patients with ischemic legs who were threatened by amputation were injected with the patients' own bone-marrow stem cells. Only seven (30 percent) of these 23 patients were not able to avoid amputation as a result of the stem cell therapy, according to Dr. Amann. (This result is most remarkable in light of the TransAtlantic Inter-Society Consensus (TASC) Report on the "Management of Peripheral Arterial Disease"—which indicated that **the expected amputation rate for this patient population is 80 percent**.) Equally important, Dr. Amann reported that concentrating bone marrow with the Harvest BMAC system made this a simple, 15-minute bedside procedure. It eliminated the risks of contaminating the sample or damaging the cells by sending the bone marrow to a specialized laboratory. With the Harvest BMAC System, Dr. Amann and other European clinicians are now able to offer stem cell therapies for vascular 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 and only technique that produces clinically significant amounts of stem and precursor cells from a small aspirate of autologous bone marrow in just 15 minutes. In Harvest's European studies, injected autologous adult stem cell concentrates from bone marrow have shown promise in achieving tissue regeneration in vascular, orthopedic and cardiovascular disease. In the U.S., the *BMAC* System is currently marketed for use in "...the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of...a cell concentrate from bone marrow."

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

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