News Release

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New stem cell treatment reduces amputations in Critical Limb Ischemia (CLI)

Data presented at "4th International Symposium on Perioperative Blood Management", Catharina Hospital, Eindhoven, The Netherlands

PLYMOUTH, Mass., Oct. 22, 2007—**Harvest Technologies Corp.** (www.harvesttech.com) announced today that **Berthold Amann, MD**, a specialist in vascular medicine, presented data ("Autologous Bone Marrow Transplantation for the Induction of Arteriogenesis: A New Treatment for Critical Limb Ischemia") from a clinical trial under his supervision at the Berlin (Germany) Vascular Center of Franziskus Hospital. He showed the results of 51 patients with end-stage Peripheral Arterial Disease (PAD), so-called ***Critical Limb Ischemia*** (CLI). Nearly all of these patients had severe pain at rest and were already scheduled for leg amputation. All surgical and endovascular options for these patients had been previously exhausted. **After the injection of a concentrate of the patients' own bone marrow stem cells, leg amputation could be avoided in more than half of these patients. This is a major success because under normal circumstances, the amputation rate in CLI is 90-100% in this patient population within a year.**

Injected autologous adult stem cell concentrates from bone marrow have been shown in international clinical studies to be significantly effective in achieving tissue regeneration in vascular, orthopedic and cardiac disease.

Until now, however, it has been difficult to process and concentrate a clinically significant dose of adult stem cells from a patient's bone marrow at the patient's hospital bedside in a simple, automated, 15-minute procedure. The **BMAC System** from Harvest Technologies is the world's first and only technique that produces clinically significant amounts of adult stem and precursor cells from a small aspirate of autologous bone marrow in just 15 minutes.

For Dr. Amann's study, he treated the first 12 patients using standard *Ficoll* separation that required 450-500 mls of bone marrow aspirate which yielded a concentrate of 1.08 billion cells. Patients had to undergo general anesthesia, and procedure time was long at 385 minutes per patient.

He then treated 39 patients with the **Harvest BMAC™ System.** With this rapid method, total procedure time per patient (i.e., anesthesia, aspiration, stem cell concentration and re-injection) was just 58 minutes per patient. Less than half the amount of bone marrow aspirate (220 mls) was needed, and the **Harvest BMAC™** stem cell concentrate had higher cell numbers than the Ficoll concentrate (3.36 billion bone marrow cells). Even more important for the patient, there was no need for general anesthesia.

At Dr. Amann's follow-up of these study-patients at periods ranging from six months to three years, 30 of 51 patients demonstrated sufficient improvement in perfusion to avoid amputation. Patients with limb salvage demonstrated an increase of critical physiological measurements: blood pressure at the ankle (ABI) and oxygen available to the foot tissue (transcutaneous oxygen). Additionally, 16 of the 30 patients whose limbs were salvaged had complete healing of their ischemic wounds.

From a patient's view, it is even more important that several patients were able to walk again; walking distance was increased tenfold among the 30 patients whose limbs were salvaged.

Based upon these positive results, Dr. Amann has undertaken a further study to establish stem-cell therapy in the treatment of patients with severe Peripheral Arterial Disease with Critical Limb Ischemia. This study will include 90 patients in a randomized, placebo-controlled, double-blind study using **Harvest BMAC™**.

(Note: The FDA has granted Investigational Device Exemption (IDE) approval to Harvest to commence a 48-patient 'feasibility' clinical trial in the U.S. using the company's BMAC System to treat patients with CLI. The BMAC System is a point-of-care device for concentrating bone marrow stem cells in approximately 15 minutes. The study's design provides for injecting a patient's own bone marrow stem cells into the affected limb to reduce the potential for limb amputation. It is believed that the injection of stem cells will induce the growth of new arteries and so arrest and possibly improve the effects of CLI. 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. Five additional major university-based medical centers are participating.)

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

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