News Release

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Berlin (Germany) Vascular Center receives IRB approval to begin clinical trial using Harvest Technologies' *BMAC*™ point-of-care system for concentrating autologous adult bone marrow stem cells to treat patients with end-stage *Critical Limb Ischemia* who face leg amputation

"I continue to believe the Harvest technology may do for regenerative medicine what 'PCR' has done for cloning genes and discovering drugs... It *is* a 'changing' technology."

Berthold Amann, MD, Vascular Medicine Specialist, Berlin Vascular Center

PLYMOUTH, Mass. Jan. 5, 2007—**Harvest Technologies Corp.** (www.harvesttech.com) announced today that Berthold Amann, MD, a specialist in vascular medicine, has received IRB approval to begin a 90-patient clinical trial at the Berlin (Germany) Vascular Center of Franziskus Hospital using Harvest Technologies' *BMAC* device—a point-of-care system for concentrating autologous bone marrow stem cells—to treat patients with end-stage *Critical Limb Ischemia* (CLI) who face leg amputation. CLI is the later stage of *Peripheral Arterial Disease* (PAD)—clogged arteries, particularly in the lower legs. Patients with CLI are at extreme risk for amputation. Reportedly, about 160,000 amputations are performed each year in the U.S. as a result of this condition (source: The Sage Group).

In a pilot study by Dr. Amann, 23 end-stage CLI patients with ischemic legs that were threatened by amputation were injected with the patients' own bone-marrow stem cells. Sixteen (70 percent) of these patients were able to have their limbs salvaged and their CLI disease arrested as a result of the stem cell therapy, according to Dr. Amann. 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* (Bone Marrow Autologous *Concentrate*) System, Dr. Amann and other European clinicians are now able to offer stem cell therapies for vascular, cardiac and orthopedic diseases.

"It's certainly no secret that autologous adult stem cells derived from bone marrow offer great promise as therapies. But the major obstacle has been that they are extremely difficult to process outside of the body—until now," said Gary Tureski, President of Harvest Technologies. "Our BMAC technology is now making it *practical* to harvest *and concentrate* them easily and quickly, at the point of care—thereby endowing European physicians such as Dr. Berthold Amann to develop non-surgical approaches for deadly diseases, *today*."

"I have previously stated for the record that Harvest's BMAC technology could be a significant step forward for not only medicine, in general, but also for treating CLI, in particular, because BMAC is fast and easy to use," said Dr. Amann. "The *concentrate* produced by the BMAC System requires a lower volume of bone marrow aspirate compared to traditional methods, is less painful, and does not require general anesthesia."

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. 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 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 is now actively in discussions with the FDA to commence a multicenter clinical trial in the United States using the BMAC System to induce the growth of new blood vessels in patients with CLI.

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

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