



*News Release*

FOR IMMEDIATE RELEASE

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**Early study results show new stem cell treatment  
successfully treats *Critical Limb Ischemia (CLI)* patients**

**First results of randomized, placebo-controlled, double-blinded study of *CLI*;  
data presented at annual meeting of the German Society of Cardiology**

PLYMOUTH, Mass., May 6, 2008 — [Harvest Technologies Corp.](http://www.harvesttech.com) ([www.harvesttech.com](http://www.harvesttech.com)) announced today that **Claas Lüdermann, MD**, a specialist in vascular medicine, presented preliminary data at the 74<sup>th</sup> Annual Meeting of the German Society of Cardiology from a clinical trial being conducted at the Berlin (Germany) Vascular Center of Franziskus Hospital under the direction of **Berthold Amman, MD**. The “**BONe Marrow Outcome Trial-2**” (BONMOT-2) is a randomized, controlled, double-blinded study treating patients with end-stage peripheral vascular disease (***Critical Limb Ischemia, or CLI***), using a cellular composition of autologous stem cells. This same treatment methodology has shown to be very promising in international clinical pilot studies, including a successful pilot study (BONMOT-1) of 60 patients recently completed under Dr. Amann’s supervision at the Berlin Vascular Center.

Dr. Ludermann presented results on the first 12 of 90 patients who completed the BONMOT-2 study protocol—six from the ***control group*** who received a placebo treatment, and six from the ***treatment group*** who received **an injection of a concentrate of their own bone marrow stem cells. The stem cell concentrate was produced at the point of care (concentrated at the patients’ bedside) using the Harvest Technologies BMAC™ System.** The treatment group showed a 100 percent improvement in perfusion (0.3 to 0.62) as measured by the *ankle-brachial index* (“ABI”) compared to the control group, which exhibited only a non-significant change in ABI (0.4 to 0.5). Increased blood supply was also confirmed by an increase of oxygen pressure in the foot, which showed the treatment group having an 18-point increase compared to a seven-point increase in the control group. The treatment group also showed an improvement in a standardized quality-of-life assessment over the control group, and also a significant improvement of 30 meters in pain-free walking compared to an increase of 10 meters for the control group.

**Dr. Lüdemann** stated: “It is encouraging that the early results of the BONMOT-2 study closely mirror the positive results obtained in our pilot study. We are optimistic that this favorable trend will continue as more study data is available.”

(more)

(Note: Harvest is supporting additional scientifically stringent CLI studies in Europe, India and the US to document the effectiveness of its Harvest BMAC™ System for a treatment option for this serious disease. In the United States 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 concentrated bone marrow containing stem cells into the affected limb to study the potential for reducing limb amputation. Stem cells induce the growth of new collateral arteries and improve the quality of life of these seriously ill CLI patients. The 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. Seven additional major university-based medical centers are participating.)

[Harvest Technologies Corp](#) is a privately held company based in Plymouth, Mass.

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