

## Harvest Technologies Announces Completion of Patient Enrollment in its 60 Patient Clinical Trial in India Using Autologous Adult Stem Cells to Treat Patients With Non-Reconstructable Critical Limb Ischemia

PLYMOUTH, Mass., July 9, 2009 -- Harvest Technologies Corp. ([www.harvesttech.com](http://www.harvesttech.com)) announced today that the company sponsored 60-patient clinical trial conducted at Sri Ramachandra Medical Center in Chennai, India using the company's BMAC System to treat patients with non-reconstructable Critical Limb Ischemia (CLI) has completed enrollment. Sri Ramachandra Medical Center is a Harvard Medical international-associated institution based in Chennai, India and one of the largest private healthcare facilities in South Asia. The study was directed by Prof. K. S. Vijayaragavan, Chief of Vascular Surgery at Sri Ramachandra University and met all regulatory approvals imposed by the Drug Controller of India and the Ethics Committee of Sri Ramachandra University, Chennai, India.

Critical limb ischemia is a persistent and relentless problem, which severely impairs the patient functional status and quality of life, and is associated with an increased cardiovascular mortality and morbidity. Prognosis of critical limb ischemia is poor and no effective treatments have been established in patients who are not amenable for the traditional revascularization therapies such as angioplasty and bypass procedures. Hence these patients have no option other than undergoing amputation or limb loss. In India a significant percentage of these patients with peripheral vascular disease are between the ages of 40 to 50. They suffer from ThromboAngitis Obliterans, which is predominant in young smokers. They have severe pain and limb loss is significant because revascularization chances are very low in these patients. Most of them end up in major amputation, lose their job and become dependant on their family to look after them.

Autologous cell therapy has been studied as an innovative treatment option for CLI, however; previously published studies did not use a rapid, point of care method for processing the cells therefore making widespread adoption of the therapy problematic. The Harvest trial utilized the BMAC system, which can process the cells in 15 minutes within the operating room. A unique feature of the trial was to compare the relative effectiveness of two different delivery methods. Thirty of the subjects received the BMAC composition by injection and thirty received the same amount of BMAC but half of the volume by injection and the remaining half by infusion into a major artery.

Prof. K. S. Vijayaragavan presented interim results on the first thirty patients treated with at least twelve weeks follow up at the Cardiovascular Research Foundation meeting on January 15, 2009 in New York City. He showed a limb salvage rate of 87.5% and significant improvement in reduction of pain, improvement in perfusion measures and in quality of life. Results on the total study population will be presented in October at the Indian Society of Vascular Surgery where the therapy will be considered for designation as a standard of care therapy.

Dr. Amit Patel, Associate Professor of Surgery and Director of Cardiovascular and Regenerative Medicine at the University of Utah School of Medicine, presented additional analysis of the interim data at the International Society for Cellular Therapy in May of 2009. Specifically, he showed data that delivering the BMAC cellular composition had a positive effect on healing wounds and that both methods of delivery showed similar results. His presentation concluded: "Based on these results, this bone marrow composition may be considered safe and has shown potential to reduce amputation rates and improve the quality of life for no-option CLI patients. This study has also shown that both the methods of delivery are equally effective and safe." "We are particularly pleased that this study is now fully enrolled and by the very promising results shown with the interim data analysis," said Gary D. Tureski, President of Harvest Technologies. "When combined with our on going multi-center FDA study in the U.S., and other studies in Germany and the Czech Republic, this study demonstrates the potential for Harvest's BMAC System to be an effective treatment for Chronic Limb Ischemia regardless of the underlying cause. We are extremely proud over 300 CLI patients have benefited from the Harvest BMAC treatment protocol."

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

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