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Harvest Technologies announces trial results in its India study using BMAC to treat patients with non-reconstructable Critical Limb Ischemia

BMAC treatment demonstrated an amputation free survival of 90%, reduced patient pain by over 90%, and reduction of the disease state by one Rutherford Class.

PLYMOUTH, Mass., Dec. 1, 2009—Harvest Technologies Corp. (www.harvesttech.com) announced today results from 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). 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 the patients with peripheral vascular disease are between the age of 40 to 50. They suffer from Thrombo Angitis Obliterans, which is predominant in young smokers. They have severe pain, open non-healing wounds and limb loss since revascularization chances are very low in these patients. Most end up with major amputation, resulting in the inability to work.

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, which enrolled the largest number of subjects of any study to date, utilized the BMAC system to process bone marrow aspirated from the patient in order to produce a highly concentrated composition of multipotent nucleated cells. The BMAC

system is unique in that it can produce this cellular composition in 15 minutes within the operating room. A unique feature of the trial was to compares 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.

The data from the 60 subjects was analyzed by an independent Contract Research Organization (Ecron Acunova, Bangalore, INDIA). The Ecron Acunova report showed that weeks 12 post treatment amputation free survival for the treated population was 90%. In addition, there was a statistically significant reduction in the subject's pain perception, increase in pain free walking distance, maximum walking distance, various perfusion measures including Regional Perfusion Index, as well as a significant improvement in the Quality of Life assessment (RAND-36 scores).

Another significant outcome, not shown in other studies, was the effect of the Harvest cell composition on the severity of the disease. CLI is a progressively degenerative disease with increasing serious in the disease being categorized by a classification system known as the Rutherford system, Rutherford classification progresses from 1 (least serious) to 6 (most serious with limb amputation imminent). All the 60 study patients were classified as either Rutherford class 4 or 5 (78% were class 5) and 12 weeks after treatment the treated cohort showed a mean reduction of one Rutherford class. "This is a truly extraordinary result," said Prof. Vijayaraghaven, "and if sustained through the end of the study will offer a significant treatment option to a patient population that has had little hope to avoid amputation."

"We are particularly pleased that the results of this study continue to show very promising results." 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 BMCA System to be an effective treatment for Chronic Limb Ischemia regardless of the underlying cause."

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

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