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Harvest Technologies announces FDA approval

Approval to begin the first randomized, clinical trial in the United States using autologous adult stem cells prepared at point of care to treat patients with congestive heart failure undergoing coronary artery bypass grafting (CABG) Surgery due to peripheral arterial occlusive disease

PLYMOUTH, Mass., October 20, 2009— Harvest Technologies Corp. (www.harvesttech.com) announced today that the Food and Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval to commence its BMAC Enhanced CABG Trial. This is a two phase 42-patient ‘feasibility’ clinical trial using the company’s BMAC System to concentrate autologous bone marrow cells to treat patients with congestive heart failure undergoing treatment with coronary artery bypass grafting (CABG) Surgery. The BMAC System is a point-of-care device used in the operating room to concentrate patient’s own (autologous) bone marrow stem cells in approximately 15 minutes. The study’s design provides for randomization of subjects into two study cohorts: Treatment Group who will have the Harvest cellular composition injected into the myocardium after CABG surgery and Control Group who will receive only the CABG surgery.

Congestive heart failure (CHF) has emerged as a major chronic disease among patients in the United States. About 400,000 new patients develop CHF each year. Morbidity and mortality rates are high; annually, approximately 900,000 patients require hospitalization for CHF, and up to 200,000 patients die from this condition. The average annual mortality rate is 40-50% in patients with severe (New York Heart Association [NYHA] class IV) heart failure. CHF accounts for over 10 million office visits, 6 million hospital days and \$30 billion in direct costs each year. The initial stages of heart failure are managed with medical therapy and the end-stage heart failure is managed with surgical procedures in addition to medical therapy. The “gold standard” surgical treatment for myocardial revascularization is coronary artery bypass grafting (CABG).

Although surgical and catheter based revascularization of ischemic myocardium can treat angina, reduce the risk of myocardial infarction, and improve function of viable myocardium, these treatments can not restore the viability of severely ischemic and/or necrotic myocardium.

Autologous cell therapy has been studied as an innovative treatment option for this patient population. Recent discoveries showing that primitive, pluripotent stem/progenitor cells may differentiate into functional myocardial or vascular tissue have ignited great interest and sparked studies utilizing these cells as a treatment strategy for acute myocardial infarction and chronic ischemic heart disease. Several papers have shown that autologous bone marrow may be the most practical and safest source for these reparative cells, as pre-clinical data suggest that subsets of bone marrow derived cells may be able to generate both functional cardiomyocytes and blood vessels.

However, two major obstacle associated with autologous adult stem cell therapy have been the lack of a simple, practical method for integrating cell therapy within the clinical setting and credible scientific-based, randomized controlled studies. “Our BMAC technology is making the benefit of cellular therapy available right now for European physicians” said Gary Tureski, President of Harvest Technologies. “They are able to harvest and concentrate autologous adult stem cells easily and quickly, at the point of care—thereby enabling them to develop cellular therapy treatments for orthopedic and vascular diseases, today. We believe that this experience will prove to be a major benefit to cellular therapy approaches for cardiac disease.”

Principal Investigator Dr. Amit Patel, MD, associate professor of surgery at the University of Utah School of Medicine, will lead this U.S. clinical study.” Having a methodology for concentrating a composition of bone marrow cells in the operating room represents the next phase in the evolution of cell based therapies for cardiac disease. The Harvest rapid bedside method can do in minutes what other methodologies used in our first series of clinical trials needed hours to complete.”

“I expect that Harvest’s BMAC technology will be a critical step forward in empowering us to offer an alternative to CLI patients who otherwise would face imminent leg amputation,” said Prof. Vijayaragavan.

“The scientific literature includes numerous studies about the therapeutic potential of autologous adult stem cells derived from bone marrow. However, the primary impediments to using autologous adult stem cell therapy have been the lack of a simple, practical method for integrating cell therapy within the clinical setting and credible scientific-based, randomized controlled studies,” said Gary Tureski, President of Harvest Technologies. “Our BMAC technology is making possible the benefit of cellular therapy right now for European physicians. Not only are they are able to harvest but also concentrate autologous adult stem cells easily and quickly, at the point of care—thereby enabling them to develop non-surgical approaches for treating vascular, cardiovascular and orthopedic diseases today.”

In a European pilot study conducted by Berthold Amann, MD, a specialist in vascular medicine at the Berlin (Germany) Vascular Center of Franziskus Hospital, 45 end-stage CLI patients with ischemic legs who were threatened by amputation were injected with the patients’ own concentrated bone marrow stem cells. After six months 62% (28/45) of this end-stage patient population were able to avoid amputation as a result of the stem cell therapy, according to Dr. Amann—in spite of the fact that 80% of these patients were scheduled for amputation prior to treatment. 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 System, Dr. Amann and other European clinicians are now able to offer stem cell therapies for vascular, cardiovascular and orthopedic diseases.

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

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