



Bioheart Reports Promising Results From Preclinical Study of Adipose-Derived Acute Cell Therapy

SUNRISE, Fla., Sept 18, 2008 /PRNewswire via COMTEX News Network/ -- A preclinical study involving the injection of adipose-derived stem cells (ADSCs) into the myocardium (heart muscle tissue) of infarcted rats, was recently completed at the Jordan University of Science and Technology in Irbid, Jordan by medical and veterinary doctors from that institution and the University of Jordan in Amman, Jordan.

The study, led by Mahmoud Abu-Abeeleh, MD, Assistant Professor of Cardiac Surgery, University of Jordan School of Medicine, Amman-Jordan, showed evidence of regeneration of cardiomyocytes (heart cells) subsequent to injection of ADSCs following heart attack, or acute myocardial infarction (AMI). The study consisted of 99 nude rats* randomized into one of six treatment arms (including a control group receiving injection-vehicle containing cell media only). ADSCs for the treatment groups were obtained from humans using the TGI 100 Cell Isolation System for collection of endothelial progenitor cells and stem cells from adipose (fat) tissue. Bioheart has secured an exclusive, worldwide license to, upon commercial approval, sell or lease the more advanced TGI 1200 System, manufactured by Tissue Genesis, Inc. for the treatment of AMI.

Upon histological analysis, the control group animals showed a tendency toward granular tissue formation (scar formation), active phagocytosis (removal of pathogens or dead cells), variable angiogenesis (new blood vessel formation) when evaluated at 10 days, early fibrosis (fibrous connective tissue formation) when evaluated at 30 days and, in some cases, established fibrosis when evaluated at 60 days. The treatment arms, however, showed a tendency toward cardiomyocyte regeneration, prominent angiogenesis (growth of new blood vessels) when evaluated at 10 days, and reduction in the infarction size when evaluated at 60 days. In some of the treated animals, minimal scarring area was observed when compared to the control group, with as much as a 90 percent reduction in myocardial scar size versus the average scar size of the control group.

*Nude rats lack an immune system, which allows for the use of human cells in preclinical studies.

These results are indicative of cardiomyocyte regeneration and suggest that the injection of ADSCs after AMI may have the potential to help the infarcted heart return to normal function.

"The study data suggest that injection of adipose-derived stem cells decreased the amount of damage from myocardial infarction by assisting in the formation of functional myocardial cells," said Dr. Abu-Abeeleh. "This is a significant and encouraging finding, which adds to the growing body of investigational evidence of using adipose-derived stem cells in the treatment of heart attacks and warrants further study of Bioheart's Acute Cell Therapy."

Fat tissue is an abundant and readily available source of endothelial progenitor and adult stem cells and is easily extractable from a patient using mildly invasive techniques.

The advanced TGI 1200 System is a compact, fully automated cell isolation system for the rapid processing of patient-derived fat tissue to separate, isolate and produce large yields of endothelial progenitor cells and stem cells. Tissue Genesis, Inc., is currently seeking certification to apply the CE Mark for commercial sale and distribution of the TGI 1200 as a tissue processing system within the European Union. The study, sponsored by Bioheart, Inc., was organized by the Philadelphia BioMed Product Development Centre, an indirect wholly owned subsidiary affiliated with a member of Bioheart's Board of Directors. Study objectives included assessment of the distribution and phenotype of the transplanted ADSCs and complete macroscopic exam and histopathology of selected tissues in a total of six differentiated study groups of approximately 15 subjects each.

A proposed pathway for seeking regulatory approval of Bioheart Acute Cell Therapy using the TGI 1200 System has been developed and additional preclinical studies involving pigs, testing for the safety and efficacy of the therapy, commenced in the first quarter of 2007 at Indiana University.

"We are very proud of our pre-clinical work with adipose-derived stem cells," said Howard J. Leonhardt, Bioheart CEO and Chief Technology Officer. "We hope that this and other pre-clinical studies will allow us to obtain IND approval for the start of a human clinical trial involving these cells for use in patients soon after they have a heart attack."

"The results of these Bioheart preclinical studies affirm our belief that the adipose-derived cells isolated from adipose tissue by the TGI System have the potential to assist in the treatment of a variety of medical conditions, including heart attacks," said Anton C. Krucky, President and CEO, Tissue Genesis, Inc. "We are excited to be associated with the foundational work of Bioheart in this area of potential heart treatment."

ABOUT ACUTE MYOCARDIAL INFARCTION

Acute myocardial infarction (heart attack), results from the sudden deprivation of circulating blood to the myocardium (heart). This results from the clogging of an artery, potentially due to a build-up of cholesterol in the inner wall of blood vessels that distribute blood to the heart muscle, or thrombosis (clot). This can lead to a part of the heart muscle becoming permanently damaged, resulting in some death of myocardial tissue (necrosis). Each year, more than one million people in the United States suffer a heart attack.

ABOUT BIOHEART, INC.

Bioheart, Inc. (Nasdaq: BHRT) is committed to delivering intelligent devices and biologics that help monitor, diagnose and treat heart failure and cardiovascular diseases. Its goals are to improve a patient's quality of life and reduce health care costs and hospitalizations. Specific to biotechnology, Bioheart is focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of chronic and acute heart damage. Its lead product candidate, MyoCell(R), is an innovative clinical muscle-derived stem cell therapy designed to populate regions of scar tissue within a patient's heart with new living cells for the purpose of improving cardiac function in chronic heart failure patients. The Company's pipeline includes multiple product candidates for the treatment of heart damage, including Bioheart Acute Cell Therapy, an autologous, adipose tissue-derived stem cell treatment for acute heart damage, and MyoCell(R) SDF-1, a therapy utilizing autologous cells that are genetically modified to express additional potentially therapeutic growth proteins. For more information on Bioheart, visit www.bioheartinc.com.

ABOUT TISSUE GENESIS, INC.

Tissue Genesis, Inc. (www.tissuegenesis.com) is a leader in adipose (fat) derived regenerative medicine solutions to address a wide range of therapeutic needs including vascular, cardiovascular, and other regenerative medical applications. The company expects its technology, expertise and products to isolate autologous adipose-derived regenerative cells at the point of care for immediate patient needs. Through its business partners, such as Bioheart, the company is extending the development and application of its technology and platform products to reach worldwide markets in the potential wide use of cell therapy.

Forward Looking Statements:

Except for historical matters contained herein, statements made in this press release are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Without limiting the generality of the foregoing, words such as "may", "will", "to", "plan", "expect", "believe", "anticipate", "intend", "could", "would", "estimate", or "continue" or the negative other variations thereof or comparable terminology are intended to identify forward-looking statements.

Investors and others are cautioned that a variety of factors, including certain risks, may affect our business and cause actual results to differ materially from those set forth in the forward-looking statements. These risk factors include, without limitation, (i) our ability to secure additional financing; (ii) the timely success and completion of our clinical trials; (iii) the occurrence of any unacceptable side effects during or after preclinical and clinical testing of our product candidates; (iv) regulatory approval of our product candidates; (v) our dependence on the success of our lead product candidate; (vi) our inability to predict the extent of our future losses or if or when we will become profitable; (vii) our ability to protect our intellectual property rights; (viii) our inability to predict the extent of our future losses or if or when we will become profitable; and (viii) intense competition. The company is also subject to the risks and uncertainties described in its filings with the Securities and Exchange Commission, including the section titled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2007, as amended by Amendment No. 1 on Form 10-K/A and its quarterly report on Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008.

SOURCE Bioheart, Inc.

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