



Bioheart Inc. Announces Positive Results in the MARVEL Phase II/III Clinical Trial

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- The MARVEL Clinical Program is designed to assess functional capacity and quality of life in patients with advanced heart failure after receiving injection of adult muscle stem cell therapy in their damaged heart muscle
- The MARVEL Phase II/III clinical trials are set to become a global benchmark study in CHF
- The 6 minute walk distance (6MWD, an established parameter of efficacy utilized in heart failure studies), one of the primary end points of MARVEL Part 1, **increased** on average by more than **91 meters** in cell-treated patients, whereas in the placebo-treated group a **decrease of nearly 4 meters** was seen
- No significant stem cell related safety concerns

Sunrise, FL September 16, 2009 – Bioheart, Inc. (OTC Bulletin Board: [BHRT](#).OB - [News](#)), presented positive efficacy data from part 1 of its Phase II/III clinical trial at the Heart Failure Society of America (HFSA) Meeting in Boston, Massachusetts. Thomas Povsic, MD, Ph.D., Assistant Professor of Medicine at Duke University, presented the final data for Part 1 of the MARVEL Phase II/III Clinical Trial as a part of the Late Breaking Clinical Trials Session. Along with Dr. Povsic, Chris O'Connor, MD, Head of Heart Failure at Duke University and the study's Principal Investigator Warren Sherman, MD, Director of Stem Cell Research and Regenerative Medicine at the Center for Interventional Vascular Therapy of Columbia University Medical Center, attended the presentation and fielded questions regarding the scientific and clinical implications of **MARVEL Part 1**.

In furthering its near-term goal of providing positive “pivotal data” of autologous skeletal myoblasts (ASM, or *MyoCell*®, Bioheart's flagship biologic product), the MARVEL Program applies study designs that emphasize *double-blind, placebo control strategies*. Dr. Povsic's presentation centered upon data from **MARVEL Part 1**, the first study of its kind to utilize **catheter-based cell delivery** in a double-blinded, placebo-controlled manner.

Patients in MARVEL Part 1, all of whom suffer from chronic heart failure and many of whom are also diabetic, were randomly assigned to three separate treatment groups: 1) *400 million cells*, or 2) *800 million cells*, or 3) *placebo*. Each injection (16 per patient) was administered directly into parts of the ventricular wall *specifically weakened by scar tissue* from previous heart attacks with the Myostar® device (Biologics Delivery Systems, Diamond Head, CA), a catheter with an established record of safety. The results presented by Dr. Povsic were based on analyses of 3 and 6-month follow-up data from 20 patients.

Over the 6-month observation period, the most pronounced changes were seen in the cell-treated groups. The 6 minute walk distance (6MWD, an established parameter of efficacy utilized in heart failure studies), one of the primary end points in the trial, **increased** on average by more than **91 meters** in cell-treated patients, whereas in the placebo-treated group a **decrease of nearly 4 meters** was seen. This may suggest that patients with heart failure could return to a more active lifestyle after receiving Bioheart's treatment. Moreover, important safety objectives were met. The occurrence of early (within 4 weeks of ASM implantation) ventricular tachyarrhythmias appeared in the ASM treated groups, similar to observations in other clinical trials involving heart failure patients. However, the arrhythmias were detected and treated with no adverse results, and disappeared in many cases early on and completely by six months post-treatment; the investigators believe that early detection and management strategies, as were implemented and refined during enrollment in MARVEL Part 1, reduce the risk of recurrent arrhythmias and may enhance 6-month event-free survival. There were no deaths in this study.

In an invited commentary immediately following the presentation, Dr. Josh Hare of the University of Miami, commended the investigators for a well designed and run clinical study. He also added that the MARVEL pivotal design utilizing a double blind placebo control should be copied for other pivotal cell therapy trials.

Dr's. Sherman and O'Connor commented on the trial, highlighting several findings and post-hoc observations. First, patient enrollment was quite brisk for a trial that randomly assigns subjects to an invasive placebo arm. While reasons for this are speculative (i.e., limited study alternatives for patients with CHF), the expertise and proficiency of the clinical sites and coordinating center were vital to the study's success, and bode favorably for subsequent studies. Second, careful evaluation of Part 1 data has directed changes to the design of MARVEL Part 2. Among these are to target a more symptomatic group of patients and to recalculate projected enrollment numbers to best achieve study endpoints. And lastly, in speaking for the entire MARVEL study group, especially the site-investigators, it was stressed that the proper perspective be maintained in drawing conclusions from a study the size of MARVEL Part 1, and that the results not be overstated. Nevertheless, the signal for improvement in 6MWD was so pronounced that all are eager to move on to the next stage.

"I see two key messages arising from MARVEL Part 1," said Dr. Sherman. "One, for years it has been very clear that certain patients with CHF derive considerable benefit from myoblast implantation. However, our clinical impressions have not been substantiated, and won't be until we have data available from a large, Phase II/III, randomized, controlled study, powered to detect the effects of these cells on meaningful clinical endpoints", he continued. "Part 2 of MARVEL will help answer this question and become a 'benchmark study'. The field is replete with 'next steps' and other studies are waiting in the wings for the ice to be broken. MARVEL will do that."

Dr. Sherman continued by saying that, "my second point is that the 'arrhythmia issue' has been overstated. Myoblasts, and other myogenic cells, are likely to induce ventricular tachycardia; it's in their nature, so to speak. But, it may also be a sign of cell engraftment and, as such, be viewed as something positive. This may sound like heresy. However, we have observed that

the arrhythmia process is controllable and only a short-term issue,” he stated. “I therefore believe it is time to shift our thinking and be open-minded to its long-term implications.”

Karl Groth, Ph.D., President and CEO at Bioheart, Inc. stated “The Part 1 results of the MARVEL trial show positive signs during treatment and an improvement in a chronic heart failure patient's ability to walk distances and be active. This means that a patient may well return to a more active lifestyle. We are committed to moving this study forward and to seeing our technology impact on the population affected by chronic heart failure.”

Dr. Thomas Povsic, the Principal Investigator at the Duke Clinical Research Institute, which helped coordinate the trial said, “We are pleased to be able to present this data to our heart failure colleagues. The MARVEL-1 trial was the first truly blinded study of intramyocardial stem cell delivery via a percutaneous approach. The results have immense implications for the design of MARVEL-2 as well as other similar trials. The improvements we observed in 6-minute walk are clinically meaningful, and this is the first time improvements have been demonstrated in relation to a blinded placebo control group. MARVEL-1 is a pilot study, but the findings are encouraging and suggest that additional trials are warranted.”

Revelations of the MARVEL Program, Bioheart’s family of clinical trials:

Part 1 of the Phase II/III clinical trial focuses on the release of an early segment of data which reveals something very important – the improvement in a Chronic Heart Failure patient's ability to walk distances. This means that the patient can be more active and may well be able to perform their daily activities better.

1. Chronic heart failure is a life-threatening condition in which a patient is virtually a cripple with no alternative but a heart transplant, or premature death.
2. The MARVEL trial uses muscle stem cells from the patient’s leg. The biopsy is shipped to Bioheart where myoblasts or muscle stem cells are isolated and expanded.
3. The muscle stem cells are cultivated to a sufficient number to inject into the donor patient, where they have proven to develop as heart muscle.
4. The MARVEL study shows a high-potential for efficacy of the myoblast treatment.
5. MARVEL is a two-part study. Careful evaluation of Part 1 data has directed changes to the design of MARVEL Part 2. Part 1 proved that the signal for improvement in 6MWD was so pronounced that all are eager to move on to the next part.

About Congestive Heart Failure

Congestive heart failure, or CHF, is a debilitating condition that occurs as the heart becomes progressively less able to pump an adequate supply of blood throughout the body resulting in

fluid accumulation in the lungs, kidneys and other body tissues. Persons suffering from NYHA Class II or worse heart failure experience high rates of mortality, frequent hospitalization and poor quality of life. Although medical therapy for CHF is improving, it remains a major debilitating condition. According to the American Heart Association Heart Disease Statistics – 2007 Update, the estimated, total direct and indirect costs of heart failure in the United States in 2006 were approximately \$33.2 billion. The AHA also estimates there to be over 5 million heart failure patients in the U.S. and an additional 500,000 patients are diagnosed with heart failure each year.

About Bioheart, Inc.

Bioheart, Inc. 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®, 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® 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.

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 obtain additional financing; (ii) our ability to control and reduce our expenses; (iii) our ability to establish a distribution network for and commence distribution of certain products for which we have acquired distribution rights; (iv) our ability to timely and successfully complete our clinical trials; (v) the occurrence of any unacceptable side effects during or after preclinical and clinical testing of our product candidates; (vi) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; (vii) our dependence on the success of our lead product candidate; (viii) our inability to predict the extent of our future losses or if or when we will become profitable; (ix) our ability to protect our intellectual property rights; and (x) 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 entitled "Risk Factors" in its Annual

Report on Form 10-K for the year ended December 31, 2008, as amended by its Annual Report on Form 10-K/A, and its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2009 and March 31, 2009.

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