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Final Data From the Bioheart Seismic Trial Suggest Safety, Efficacy of Autologous Stem-Cell Therapy for Treating Congestive Heart Failure

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Leading Expert Discusses Study During Late-Breaking Presentations at ACC

CHICAGO, April 1, 2008 /PRNewswire-FirstCall/ -- Bioheart, Inc. (Nasdaq: BHRT - News) announced today that final six-month, follow-up patient data was presented today during the late-breaking clinical trial sessions at the American College of Cardiology, suggesting that MyoCell® myoblast clinical cell therapy is a safe and potentially effective alternative treatment to standard medical therapy alone for improving heart function among patients with previously implanted cardiac devices who are experiencing congestive heart failure.

The findings from the SEISMIC(1) Trial, a 40-patient, randomized, multicenter, controlled, Phase II-a study conducted in Europe, evaluated MyoCell myoblast clinical cell therapy delivered via the MyoCath®, endoventricular needle-injection catheter in patients previously fitted with implanted cardiac defibrillators(ICDs), receiving standard medical therapy and who are experiencing congestive heart failure. On admission to the trial, patients were randomized on a two-to-one ratio into the treatment versus control groups with 26 patients receiving MyoCell therapy and 14 patients in the control group. All patients were experiencing congestive heart failure and were previously fitted with ICDs and receiving standard medical therapy. Both the MyoCell biologic therapy and the MyoCath needle-injection catheter, developed by Bioheart, Inc., are currently being studied as investigational products.

"The results from the SEISMIC Trial are encouraging," said Prof. Patrick W. Serruys, MD, PhD, Principal Investigator and Chief, Department of Interventional Cardiology, Thoraxcenter, Erasmus Medical Center - Rotterdam, the Netherlands. "While the study was specifically designed to show safety, the findings also suggest positive trends in clinical benefits when evaluating the treated group versus the control group at six months."

Patients in both groups were evaluated at three- and six-month intervals using a variety of tests, including digital imaging and standard quality of life measurement such as the six-minute walking test, New York Heart Association (NYHA) heart failure classification and Minnesota Living with Heart (MLHF) questionnaire. Final six-month results observed in the SEISMIC Trial include:

- 84 percent of treated patients experienced improved or unchanged six-minute walking test scores compared to 16 percent of the control group
- 69 percent of the control group's results worsened, versus only 16 percent of the treated group
- 94 percent of treated patients experienced improved or unchanged NYHA classification compared to 58 percent of the control group
- 42 percent of the control group's results worsened, versus only 6 percent of the treated group

Prof. Serruys also noted that reports of arrhythmia among the patients evaluated in SEISMIC, both in terms of total number of episodes as well as timing of episodes, were no different between the treatment and control arms in the study. This suggests that MyoCell is not associated with a higher prevalence of arrhythmias; rather, that arrhythmias are an expected occurrence for this subset of heart failure patients.

"These data support the need for a randomized, double-blind, placebo-controlled study involving the MyoCell technology," said Prof. Serruys. "We look forward to applying our learning from this trial to the larger, more comprehensive MARVEL(2) Trial currently underway in the U.S. and Europe."

The MARVEL Trial, a randomized, double-blind, placebo-controlled, multi-center Phase II/III Trial involving 330 patients in North America and Europe, is the largest trial of its kind to date. Enrollment in the MARVEL Trial began in October 2007, targeting patients who fall into Class II or III heart failure. The MARVEL Trial will further study the safety and efficacy of the minimally invasive MyoCell autologous stem-cell therapy in the treatment of congestive heart failure delivered via a MyoStar(TM) injection catheter(3), in combination with the NOGA® XP Cardiac Navigation System. The Principal Investigator for the MARVEL Trial is Warren Sherman, MD, Director, Cardiac Cell-based Endovascular Therapies, Columbia University Medical Center, New York.

ABOUT MYOCELL CLINICAL CELL THERAPY

MyoCell clinical cell therapy, developed by Bioheart, Inc., is currently being studied as an investigational product in Europe and the U.S. MyoCell clinical cell therapy is intended to be used to improve cardiac function months or even years after a patient has suffered severe heart damage due to a heart attack. The procedure involves a physician removing a small amount of muscle obtained from the patient's thigh. From this muscle specimen, autologous myoblasts (muscle stem cells) are then isolated, grown using Bioheart's proprietary cell-culturing process, and injected directly into the scar tissue of the patient's heart. The myoblast cells are delivered via an endoventricular needle-injection catheter during a minimally invasive procedure performed by an interventional cardiologist or vascular surgeon. The myoblast-based muscle formation in the newly populated regions of scar tissue are intended to improve cardiac function by helping the heart muscle beat more efficiently.

ABOUT HEART DISEASE

Approximately nine million European patients and 5.2 million Americans(4) suffer from congestive heart failure, a progressively degenerative condition in which the heart is unable to adequately pump blood throughout the body resulting in fluid accumulation in the lungs, kidneys, and other body tissues. Patients suffering from this disease fatigue easily, and become increasingly less capable of normal activity as they progress through the various stages of the disease. Current standard of care typically involves drug therapy and/or the implantation of a pacemaker and/or defibrillator device to regulate heart function.

ABOUT BIOHEART, INC.

Bioheart, Inc. is a biotechnology company 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 cell therapy designed to populate regions of scar tissue within a patient's heart with autologous muscle cells, or cells from the patient's body, 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 cell treatment for acute heart damage, and MyoCell SDF-1, a therapy utilizing autologous cells genetically modified to express additional growth factors.

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 (ix) intense competition. The Company is also subject to the risks and uncertainties described in its filings with the Securities and Exchange Commission, including Post-Effective Amendment No. 5 to its Registration Statement on Form S-1 (Registration No. 333-140672) filed on February 13, 2008.

FOOTNOTES

- (1) SEISMIC: Safety and Effects of Implanted (Autologous) Skeletal Myoblasts (MyoCell®) using an Injection Catheter
- (2) MARVEL: A Phase II/III, Double-Blind, Randomized, Placebo-Controlled Multi-center study to Assess the Safety and Cardiovascular Effects of MyoCell Implantation by a Catheter Delivery System in Congestive Heart Failure Patients Post-Myocardial Infarction(s)
- (3) The MYOSTAR(TM) Injection Catheter is not available for sale in the U.S. It is in use in IND investigations
- (4) Heart Association Heart Disease Statistics - 2007 Update

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MyoStar and NOGA XP are trademarks of Cordis Corporation, a Johnson & Johnson company

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