



## United States FDA Clears the REGEN Trial to Test Bioheart's Combination Gene and Stem Cell Therapy in Heart Failure Patients

SUNRISE, Fla., July 28, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Bioheart, Inc., (OTC Bulletin Board: BHRT) a company committed to delivering intelligent devices and biologics that help monitor, diagnose and treat heart failure and cardiovascular diseases announced today that the US FDA cleared a phase I clinical trial for MyoCell SDF-1 (Stromal Derived Factor - 1) to treat congestive heart failure. The REGEN trial will enroll 15 patients in a multicenter, randomized, dose escalation study to assess the safety and cardiovascular effects of the implantation of MyoCell SDF-1 in congestive heart failure patients post myocardial infarction(s).

MyoCell SDF-1 is a composition of myogenic stem cells derived from a patient's own thigh muscle that has been modified to over express the SDF-1 protein. The product candidate is prepared with an 18-step proprietary method in a cGMP laboratory. Utilizing a needle-tipped catheter inserted into the groin of a patient who is suffering from heart failure, the cells are injected into the scar tissue that has formed in the patient's heart. The goal of MyoCell SDF-1 is to grow new contractile muscle within the scar tissue that will have the ability to release additional beneficial proteins to assist in the tissue repair process and improve the patient's heart function, exercise capacity and quality of life. In preclinical studies, MyoCell SDF-1 provided a 54 percent improvement of heart function compared to 27 percent for the original MyoCell composition while the placebo control treated animals declined by 10 percent. The preclinical studies also demonstrated that this product candidate can enhance blood vessel formation in damaged hearts.

"We are happy to be able to begin the REGEN trial to test this promising product candidate in heart failure patients after completing very successful preclinical testing," said Howard Leonhardt, Bioheart's Chairman and CEO. "To our knowledge, this will be the first clinical trial ever to test a combination gene and stem cell therapy for cardiovascular disease."

The U.S. trial is expected to begin this year. After completing the REGEN safety protocol with one-month follow-up, the company hopes to transition this second-generation product into its FDA-authorized Phase II/III MARVEL study. MyoCell SDF-1 is substantially similar to the original MyoCell composition that has been active in clinical trials since early 2001 at more than 50 centers worldwide.

The patents Bioheart has acquired covering the myogenic cells and SDF-1 compositions and methods are expected to provide intellectual property protection until 2023.

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((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](http://www.bioheartinc.com).

MyoCell and MyoCell SDF-1 are trademarks of Bioheart, Inc.

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 March 31, 2008; June 30, 2008 and September 30, 2008.

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