

Bioheart's Appeals to the FDA for Compassionate Use Designation to Save Lives

/EINPresswire.com/ Mike Tomas President/CEO said, "Knowing this information, we believe the ethical choice is to make the drug available on a [compassionate use](#) basis."

SUNRISE, FL, Mar 27, 2013 — Bioheart, Inc. (otcqb:BHRT) today announced that the Company is preparing to request of the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) permission to allow access to investigational drugs outside of a clinical trial setting. Bioheart's cell therapy products address an unmet need in the cardiac market by providing true regenerative medicine where the [MyoCell\(R\)](#) product line may regenerate muscle in areas of scar tissue and the [LipiCell\(R\)](#) product may help reduce inflammation and promote the growth of new blood vessels.

Expanded access, sometimes called "compassionate use," is the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial.

"We decided to initiate this program as we have had a continuing large number of requests by physicians and patients to make MyoCell(R) and LipiCell(R) available on a compassionate basis," said Mike Tomas President/CEO of Bioheart. "Preliminary analysis of interim data results from our cardiac products and centers of excellence suggests that we can safely provide MyoCell(R) and LipiCell(R) for treatment of selected cardiac patients, and that the agent has potential to benefit some of these patients. Knowing this information, we believe the ethical choice is to make the drug available on a compassionate use basis."

Information about the Company's clinical trials can be found at the NIH registry, www.clinicaltrials.gov. Interested parties are encouraged to visit Bioheart's website, <http://www.bioheartinc.com>, where details on the compassionate use program and additional information will be posted in the near future.

About Bioheart, Inc.

Bioheart is committed to maintaining its leading position within the cardiovascular sector of the

cell technology industry delivering cell therapies and biologics that help address congestive heart failure, lower limb ischemia, chronic heart ischemia, acute myocardial infarctions and other issues. Bioheart's goals are to cause damaged tissue to be regenerated, when possible, and 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 and peripheral vascular disease. Its leading product, MyoCell, is a clinical muscle-derived 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. For more information on Bioheart, or visit us on Facebook: Bioheart and Twitter @BioheartInc.

Forward-Looking Statements: Except for historical matters contained herein, statements made in this press release are forward-looking statements. 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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The Company is 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, 2011, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

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