



## **ASX ANNOUNCEMENT**

### **Single Center Data from C-Pulse® Feasibility Trial in Patients with Moderate to Severe Heart Failure to be Presented at the 2012 ISMICS Annual Meeting**

#### ***Findings from Single Center Highlight Minimally Invasive Thoracotomy Implantation Technique of Novel Counter-Pulsation Cardiac Device***

**Sydney, Australia and Eden Prairie, MN: May 31, 2012:** Sunshine Heart, Inc. (NASDAQ: SSH / ASX: SHC), a global medical device company focused on innovative technologies for moderate to severe heart failure, today announced data from a single center participating in the U.S. Food and Drug Association (FDA) feasibility clinical trial for the C-Pulse® Heart Assist System will be presented at the 2012 International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) Annual Meeting in Los Angeles, May 30-June 2, 2012. Findings from a single center utilizing the C-Pulse System demonstrated that the device can be safely implanted utilizing a minimally invasive approach. The C-Pulse System is a new investigational therapeutic approach based on proven balloon counter-pulsation technology for the treatment of patients with Class III and ambulatory Class IV heart failure.

The data will be presented by Sanjeev Aggarwal, M.D., director of Mechanical Circulatory Support at St. Luke's Mid America Heart Institute, during the cardiac track on heart failure. The oral presentation, titled "Results of the C-Pulse Prospective Feasibility Study for the Treatment of Ambulatory Heart Failure Utilizing A Minimally Invasive Thoracotomy Implantation Technique," will be held Saturday, June 2 at 8:30-9:50 a.m. P.D.T.

"The C-Pulse device represents an important advance in the treatment of patients suffering from heart failure," said Dr. Aggarwal. "It offers the opportunity to provide a means of mechanical circulatory support using a minimally invasive procedure without direct blood contact, offering a favorable risk profile without the need for systemic anticoagulation."

Five patients underwent implantation of the C-Pulse System at a single institution participating in the FDA approved investigational device exemption (IDE) prospective feasibility study. Primary safety endpoints included death, aortic disruption, neurologic events, myocardial infarction and major infection at six months. Quality of life was assessed using Minnesota Living with Heart Failure (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ). One patient underwent implantation of the device using a hemi-sternotomy approach. Four patients underwent placement using a limited right parasternal thoracotomy incision, leaving the sternum intact. All patients were New York Heart Association (NYHA) Class III at baseline, with non-ischemic etiology in four out of five patients. Mean follow up was 351 days (range 64-498) with 1,754 total patient days with four patients still on device therapy.

The findings showed significant improvements at 6 months in MLWHF scores [baseline mean 50 (range 20-71) versus mean 31 (range 5-49) at 6 months] and KCCQ scores [baseline mean 56 (range 37-81) versus mean 69 (range 52-92)]. There was also a one to two class

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improvement in NYHA in the majority of the patients. There were no deaths, aortic disruptions, neurologic events, myocardial infarctions or mediastinal infections reported.

“Dr. Aggarwal was the leading implanter of the C-Pulse System and we want to thank him and the staff at St. Luke’s Mid America Heart Institute for their support during and after the trial,” said Dave Rosa, chief executive officer of Sunshine Heart. “We are encouraged by the results from the feasibility trial and we look forward to further studying the device in a prospective, multi-center, randomized control trial. We are on track to begin the U.S. pivotal trial in the second half of 2012.”

### **About Class III Heart Failure**

Heart failure is a common condition in which the heart becomes unable to pump sufficient blood to meet the body’s needs. More than five million people in the United States have heart failure, resulting in more than 300,000 deaths each year<sup>1</sup>. Heart failure is a progressive condition and typically results from damage to the heart muscle arising from a heart attack or virus. Cardiologists use the New York Heart Association (NYHA) classification system to define the four classes of heart failure; each class is determined by rating a patient’s symptoms to everyday activities and quality of life. More than 1.5 million U.S. heart failure patients are in the Class III or moderate heart failure category which is defined by the limitation of physical activity<sup>2</sup>. These patients are comfortable at rest, but levels of activity regarded as less than ordinary cause fatigue, palpitation and/or shortness of breath. The most common treatments for Class III heart failure are drugs, lifestyle adjustments, family education, device therapy (i.e. heart failure pacemaker with or without a defibrillator) or surgery. These standard treatments often do not resolve the progression of heart failure leaving patients without any additional options, hence the need for new treatments for patients living with the disease.

### **About The C-Pulse® Heart Assist System**

The C-Pulse® Heart Assist System, an investigational device, utilizes the proven scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Operating outside the patient’s bloodstream, the novel extra-aortic approach of the C-Pulse technology offers greater flexibility allowing patients to disconnect as necessary or desired. The C-Pulse System’s potential benefits may help reverse the heart failure process or maintain the patient’s current condition, which may reduce the need for later stage heart failure therapies, such as left ventricular assist devices (LVADs), artificial hearts or transplants.

**Caution** – Investigational device. Limited by Federal (or United States) law to investigational use.

### **About Sunshine Heart®**

Sunshine Heart, Inc. (NASDAQ: SSH / ASX: SHC) is a global medical device company committed to the commercialization of the C-Pulse Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure. The C-Pulse System can be implanted using a minimally invasive procedure and is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology, which enables an increase in cardiac output, an increase in coronary blood flow and a reduction in the heart’s pumping load. The Company has completed an approved U.S. Food and Drug

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Administration (FDA) feasibility clinical trial of the C-Pulse System and presented the results in

November 2011. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with a subsidiary presence in Australia. The Company has been listed on the ASX since September 2004 and on NASDAQ beginning February 2012. For more information, please visit [www.sunshineheart.com](http://www.sunshineheart.com).

### **Forward-Looking Statements**

Certain statements in this report are forward-looking statements that are based on management's beliefs, assumptions and expectations and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations with respect to product development and commercialization efforts, results of clinical trials, timing of regulatory filings and approvals, regulatory acceptance of our filings, research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of the products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the U.S. Securities and Exchange Commission (SEC) and ASX could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of the C-Pulse Heart System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the ASX and SEC. We may update our risk factors from time to time.

<sup>1</sup> <http://www.nlm.nih.gov/medlineplus/heartfailure.html>

<sup>2</sup> LSI (Life Science Intelligence) Report, # 0515-1-US-1010-206, 11/2010

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