Sunshine Heart Receives Health Canada Approval to Modify Its Ongoing Investigational Study to Use the Next Generation C-Pulse(R) System Driver

The Associated Press

Sunshine Heart, Inc. (NASDAQ: SSH) (ASX: SHC), a global medical device company focused on innovative technologies for moderate to severe heart failure, today announced that the company has been granted approval by Health Canada to use its next generation C-Pulse@ Heart Assist System driver in ongoing clinical studies at Royal Victoria Hospital. The new C-Pulse driver is designed to provide heart failure patients with enhanced patient comfort and performance. 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 C-Pulse driver now comes as a single unit that is half the size, lighter and quieter than the first generation technology. The driver also features a number of software enhancements. The C-Pulse System is currently in an investigational study at Royal Victoria Hospital. The prospective study is designed to evaluate the safety and performance of the C-Pulse System as a treatment for patients with moderate to severe heart failure. To date, four patients have been implanted with the initial C-Pulse System. The company has received Health Canada approval to expand the number of participants in the trial to 20

patients. All trial participants will receive the new C-Pulse driver, which will be used in ongoing and future clinical studies.

"We are pleased to have received Health Canada approval of our next generation C-Pulse driver technology for clinical use," said Dave Rosa, CEO of Sunshine Heart. "We enhanced the driver based on results from our feasibility trial and feedback from physicians and patients. With the reduced size, weight and noise reduction, we expect improvements in patient quality of life due to enhanced comfort and performance. We look forward to making this new technology available to patients enrolled in our clinical studies in Canada in the coming weeks, as well the United States and Europe thereafter."

The external C-Pulse driver inflates and deflates the balloon which is secured by a cuff around the outside of the ascending aorta, the main blood vessel of the heart. The cuff and heart signal sensing wires are attached to the external C-Pulse driver, which inflates and deflates the balloon in sequence with the electrocardiogram (ECG) signal to assist heart function and the pumping capacity of the heart. The balloon deflects the aorta in a "thumb-printing" manner, which is intended to minimize aortic wall strain and maximize blood volume displacement per beat.

About Class III Heart FailureHeart 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(1). 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(2). 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 SystemThe 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 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.

(1)

http://www.nlm.nih.gov/medlineplus/heartfailure.html(http://www.nlm.nih.gov/medlineplus/heartfailure.html)

(2) LSI (Life Science Intelligence) Report, # 0515-1-US-1010-206,

11/2010

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