ASX Announcement

Sunshine Heart Announces Ohio State's Release of Early Results in C-Pulse Feasibility Trial

Results show positive efficacy trend and strong safety profile

Sydney, Australia and Eden Prairie, MN; September 22, 2011: Sunshine Heart, Inc. (ASX: SHC), today announced Ohio State's release of early results of a six month feasibility study utilizing Sunshine Heart's minimally invasive C-Pulse system for Class III and ambulatory Class IV heart failure.

Ohio State's full release (below) can also be viewed at: http://medicalcenter.osu.edu/mediaroom/releases/Pages/Early-Results-Promising-for-New-Heart-Failure-Therapy-Device.aspx.

Sept. 21, 2011

EARLY RESULTS PROMISING FOR NEW HEART THERAPY DEVICE

COLUMBUS, Ohio – Patients with moderate to severe heart failure, who were enrolled in a feasibility study of a new device which resembles a blood pressure cuff and is wrapped around a patient's ascending aorta to improve cardiac performance, saw improvements in a number of indicators and researchers believe those results warrant a larger pivotal trial.

"The trial results to date show positive trends of efficacy with a strong safety profile as compared to later stage mechanical support devices," says Dr. William T. Abraham, director of the division of cardiovascular medicine at the Ohio State University Medical Center, and national co-lead principal investigator. "We believe further investigation is needed as hundreds of thousands of heart failure patients in this country remain substantially symptomatic despite currently available treatments."

The trial results will be presented in detail during the Transcatheter Cardiovascular Therapeutics Meeting on Nov. 8.

The multi-center trial was led in part by Ohio State's Medical Center, where a West Virginia man and a central Ohio man became the first in the United States to receive the device in 2009.

Twenty patients, eight women and 12 men with an average age of 56, were enrolled in the North American trial. Eighteen patients were classified with New York Heart Association (NYHA) Class III heart failure and two were Class IV, the most severe forms of heart failure. For these patients, daily activities such as walking across the room, moderate exercise or climbing stairs can be a challenge. All patients had cardiac resynchronization therapy, implantable cardiac defibrillators or combination devices implanted. Three patients were successfully bridged to transplant with one patient being supported for 22 months, the longest of any patient participating in the trial.

All but one patient either improved or maintained NYHA heart failure classification. Two patients were disconnected permanently, one after eleven months on therapy due to the absence of heart failure symptoms. Overall, other improvements were realized as measured by quality of life scores, six-minute walk times, ejection fractions, or the heart's pumping ability, and reductions in medications. One patient death from an aortic disruption was reported as a result of a re-sternotomy surgery to treat a procedure related infection. No neurologic events or heart attacks were reported, while six superficial exit site

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infections were successfully treated with antibiotics. There was one instance of post operative, non-device related bleeding.

Once implanted, the system uses an ECG sensing wire and rapidly inflates and deflates to assist the pumping action of the heart. While implanted minimally invasively or during an open chest procedure, an advantage of this therapy is that it avoids blood contact, which limits complications and allows for faster recovery time. Patients had a median length of hospital stay of eight days.

When the heart is filling with blood, the cuff inflates to push blood out of the aorta to the rest of the body and to the heart muscle itself. Just before the heart pumps blood out, the device deflates to open up the aorta, reducing aortic pressure and the heart's workload.

According to Abraham, heart failure occurs when a patient's heart is not pumping blood efficiently, most often due to a weak heart muscle damaged by a prior heart attack or some other cause. More than five million U.S. adults suffer from heart failure, with an estimated 500,000 new cases each year.

OSU Medical Center, a leading center for heart failure and interventional research, was one of seven centers participating, and the only one in Ohio, in the FDA-approved safety and feasibility study.

The device, the C-Pulse Heart Assist System, has FDA Investigational Device Exemption (IDE) approval for investigational use only and was developed by Sunshine Heart, Inc., Eden Prairie, MN. The study was funded by Sunshine Heart, Inc. Abraham is a paid consultant for the company.

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Click here for a high quality JPEG of Dr. William Abraham

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About the C-Pulse Heart Assist System

C-Pulse Heart Assist System utilizes an extra-aortic approach to proven intra-aortic balloon counter pulsation technology 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 Heart Assist's potential benefits may help reverse the heart failure process or maintain the patient's current condition, thereby preventing the need for later stage heart failure devices, such as left ventricular assist devices (LVADs), artificial hearts or transplants.

About Sunshine Heart

Sunshine Heart (ASX: SHC) is a global medical device company committed to novel cardiac and coronary therapy. The company is currently developing the C-Pulse® Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure which can be implanted using a minimally invasive procedure. C-Pulse is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling an increase in cardiac output, an increase in coronary blood flow, and a reduction in the heart's pumping load. The company has received approval from the U.S. Food and Drug Administration to conduct a U.S. feasibility clinical trial with the C-Pulse System. Sunshine Heart is a Delaware-based corporation headquartered in Minneapolis, MN, with a subsidiary presence in Australia. The company has been listed on the Australian Securities Exchange (ASX) since September 2004. For more information, please visit www.sunshineheart.com.

Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address 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 the progress of, and presentation of data related to product development and commercialization efforts, results of clinical trials, expected timing of FDA regulatory filings, FDA acceptance of our filings and research and development activities, ultimate clinical outcomes and benefit of the Company's products to patients, market and physician acceptance of the products, intellectual property protection and competitive product offerings 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 the FDA does not accept our regulatory application or approve the marketing of the C-Pulse® Heart Assist System in the U.S., and those described in our filings with the ASX. We may update our risk factors from time to time in our filings with the ASX.

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