



**ASX Announcement**

**Monday 11 April 2011**

**Sunshine Heart Receives Approval to Expand C-Pulse®  
Heart Assist System Study**

***– FDA Allows Enrollment of Up to 20 Additional Patients and Two New Trial Sites –***

**SYDNEY Australia 11 April 2011:** Sunshine Heart, Inc (ASX: SHC), a global medical device company focused on innovative technologies for Class III/ambulatory Class IV (moderate to severe) heart failure, today announced the United States Food and Drug Administration (FDA) had approved the Company's investigational device exemption (IDE) supplement for the C-Pulse® Heart Assist System.

The FDA expansion protocol approval permits the Company to implant an additional 20 patients and to add two new study sites. The Company recently announced that the C-Pulse® Heart Assist System has been implanted in 20 patients globally.

"We are pleased that the FDA has approved our request to continue to offer this therapy to additional patients that meet the appropriate criteria while we collect the follow-up data from our initial twenty patients," said Dave Rosa, Sunshine Heart's CEO. "This will allow not only existing centers to continue to offer the therapy but it will also enable us to add two additional sites that have expressed interest in participating."

The C-Pulse feasibility study is primarily designed to assess safety and provide indications of performance of this device in moderate to severe heart failure patients who suffer from symptoms such as shortness of breath and reduced mobility. Once the six-month follow-up with the 20th patient is completed, Sunshine Heart will submit the feasibility data to the FDA. Shortly thereafter, the company will seek FDA approval for the pivotal trial protocol.

The FDA-approved IDE feasibility study is available to men and women between the ages of 18 to 75 who suffer from Class III/ambulatory Class IV heart failure and for whom standard drug therapy has failed. For additional information, please visit [www.sunshineheart.com](http://www.sunshineheart.com) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About the C-Pulse Heart Assist System**

Using intra-aortic balloon counter-pulsation technology, the C-Pulse Heart Assist System assists the left ventricle by reducing the workload required to pump blood throughout the body. In addition, it increases blood flow to the coronary arteries. Combined, these 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.

Once implanted, the C-Pulse cuff is positioned on the outside of the patient's ascending aorta above the aortic valve. An ECG sensing lead is then attached to the heart to determine timing for cuff inflation and deflation in synchronization with the heartbeat. The C-Pulse cuff and electrical leads are connected to a single line that is run through the abdomen to connect to a power driver outside the body. Because the C-Pulse System remains outside the blood system, there is potentially less risk of blood clots and stroke in comparison to other mechanical devices that reside or function in the bloodstream.

The C-Pulse System is an earlier intervention than other mechanical therapies, such as LVADs. This device does not directly contact the patient's blood and it may be turned on or off at any time allowing the patient intervals of freedom to perform certain activities. The C-Pulse System may also be implanted via a minimally invasive procedure, which may reduce procedural time, hospital stays, overall cost and patient risk as compared to a traditional sternotomy.

### **About Sunshine Heart**

Sunshine Heart (ASX: SHC) is a global medical device company committed to the commercialization of the C-Pulse<sup>®</sup> 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 ASX since September 2004. For more information, please visit [www.sunshineheart.com](http://www.sunshineheart.com).

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