Sunshine Heart Receives Unconditional FDA Approval for C-Pulse® System's U.S. Pivotal Trial

Eden Prairie, MN and Sydney, Australia: November 20, 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 it has received unconditional approval from the FDA to commence its pivotal U.S. trial for its flagship C-Pulse® Heart Assist System

"We are pleased to have expeditiously completed the approval process with the FDA. We are excited to evaluate the C- Pulse System's potential in treating patients suffering from Class III and ambulatory Class IV heart failure. We also are eager to evaluate its clinical and economic impact in reducing re-hospitalization rates due to worsening heart failure as this represents the highest and most costly re-hospitalization rates plaguing the U.S. healthcare system today. All of us at Sunshine Heart are committed to expediting this next phase of technology advancement" commented Dave Rosa.

Sunshine Heart plans to initiate the pivotal trial in North America in the fourth quarter of 2012. The Company has contacted a number of leading heart failure centers in the U.S. and to date is encouraged by the positive response to participate in the trial. The trial design will consist of 388-patients of which half will be implanted with the C-Pulse System. The other half will be randomized to optimal medical therapy across 30-40 clinical sites. Sunshine Heart expects to receive revenues from trial sites for device implants as the FDA has granted CMS Category B3 status. Because of this designation, it is also anticipated that participating trial centers will be reimbursed by CMS and most private insurance providers. The trial will utilize the Company's next-generation single unit C-Pulse driver, which received approval for clinical trial use from the FDA in August, 2012, and has been in use in Canadian and U.S. patients currently on the device. The new driver features a single unit, which is lighter, quieter, approximately half the size of its predecessor, and also includes numerous software updates.

In July, Sunshine Heart announced positive 12-month extended follow-up data from its preliminary feasibility study of the C-Pulse® Heart Assist System. Extended data included positive efficacy trends with continued improvements in NYHA Class reduction, MLWHF Quality of Life score, and six minute hall walk. There were no additional patients with device-related serious adverse events (SAEs) in this 12 month time frame. Also in July, the Company achieved CE Mark certification, allowing commercialization of the device in Europe. The Company has been targeting leading LVAD and transplant centers in the EU. Specific initial focus for the device has been within Germany and Italy, two countries that when combined, are believed to have the highest number of hospital bed days per year for heart failure in Europe.

The Company estimates enrollment for the event-driven pivotal trial will take approximately 2.5 years. The primary endpoint of the trial will be reduction in worsening heart failure events leading to hospitalization, advanced heart failure therapies and heart failure related mortality. A one year safety follow-up is expected. The lead investigator for the trial will be Dr. William T. Abraham, Director of the Division of Cardiovascular Medicine at The Ohio State University Medical Center.

About the C-Pulse® Heart Assist System

The C-Pulse Heart Assist System, or C-Pulse System, an investigational device in the United States, Canada and countries that do not recognize the CE Mark approval, utilizes the 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 extra-aortic approach of the C-Pulse technology offers greater flexibility, allowing patients to safely disconnect to have intervals of freedom to perform certain activities such as showering. The C-Pulse System may help maintain the patient's current condition and, in some cases, reverse the heart failure

process, thereby potentially preventing 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 an early-stage global medical device company committed to the commercialization of the C-Pulse 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. Sunshine Heart 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. In March, 2012, the FDA notified the Company that it could move forward with an investigational device exemption (IDE) application. Sunshine Heart received conditional approval from the FDA in September 2012 to initiate its pivotal trial. In July 2012 Sunshine Heart received CE Mark approval for its C-Pulse System in Europe. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with a subsidiary presence in Australia. The Company has been listed on the Australian Securities Exchange (ASX) since September 2004 and on the NASDAQ Capital Market since February 2012. For more information, please visit www.sunshineheart.com.

Forward-Looking Statements

Certain statements in this release 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 future clinical trial activities and results including patient enrollment in trials. These forward-looking statements are subject to numerous risks and uncertainties, including without limitation, the possibility that our clinical trials do not meet their enrollment goals, meet their end-points or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, that we may not be able to commercialize our products successfully in the EU and the other risk factors described under the caption "Risk Factors" and elsewhere in our filings with the U.S. Securities and Exchange Commission and ASX. You should not place undue reliance on forward-looking statements because they speak only as of the date when made and may turn out to be inaccurate. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We 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.

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