ASX Announcement

Sunshine Heart Announces FDA Completes Review of C-Pulse® Feasibility Data

Next Up: Submission of U.S. Pivotal Trial Protocol

Sydney, Australia and Eden Prairie, MN: 14 March, 2012: Sunshine Heart, Inc. (NASDAQ: SSH, ASX: SHC) today announced that the Center for Devices and Radiological Health(CDRH) of the United States Food and Drug Administration(FDA) completed its review of Sunshine Heart's Investigation Device Exemption(IDE) for the C-Pulse Heart Assist System feasibility trial. The FDA notified the Company that it has met the requirements of FDA regulation 21CFR 812.150(b)(5) and that no other information is required at this time.

Following the communication from the FDA, Dave Rosa, CEO of Sunshine Heart commented, "We are pleased that we have fulfilled the agency's requirements and look forward to working with the FDA regarding the submission of our pivotal trial protocol."

The Company continues to expect that the C-Pulse U.S. pivotal trial will commence in the third quarter as previously forecast.

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 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 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 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 enrollment of an approved U.S. Food and Drug Administration (FDA) 20 patient feasibility clinical trial with the C-Pulse System. 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 since February 2012. 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 product development and commercialization efforts, results of clinical trials, expected timing of regulatory filings and approvals, regulatory acceptance of our filings and research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of the products, intellectual property protection, competitive product offerings and the other risk factors described in our filings with the 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 regulatory authorities do not accept our application or approve the marketing of the C-Pulse® Heart Assist System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, the possibility we may be unable to successfully list our securities on a U.S. securities exchange, 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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