



## **ASX Announcement**

### **First Female Patients in US Implanted with C-Pulse**

**Sydney, California [10 August 2009]** - Sunshine Heart, Inc. (ASX: SHC), a global medical device company focused on innovative technologies for advanced heart failure, announced today that Jewish Hospital in Louisville, Kentucky has completed implants of the Company's C- Pulse™ heart assist system in two female patients, ages fifty-eight and fifty-five, respectively, under a clinical trial approved by the US Food and Drug Administration (FDA). These procedures mark the first US female patients and the third and fourth patients treated with the C-Pulse heart assist system.

The C-Pulse system was implanted by Dr Mark Slaughter, Professor of Surgery and Chief of the Division of Thoracic and Cardiovascular Surgery at the University of Louisville. Dr Slaughter is a renowned cardiothoracic surgeon who also serves as the Director of the Heart Transplant and Mechanical Assist Device program at Jewish Hospital and the University of Louisville and is the Associate Medical Director of the Cardiovascular Innovation Institute.

"It is an honour to have completed the first US implants of the C-Pulse heart assist system in female heart failure patients," said Dr Slaughter. "C-Pulse is highly innovative and implanted with a simple, low-risk minimally invasive surgical procedure. The device has the potential to offer a new therapy option for the treatment of advanced heart failure."

"We are excited to be a part of the C-Pulse clinical trial in the US," said Dr Sumanth Prabhu, Professor of Medicine and Physiology and Director of Heart Failure at the University of Louisville and Co-Principal Investigator of the trial at Jewish Hospital. "The C-Pulse system is a novel device that increases blood flow to the body and to the heart muscle itself without coming into direct contact with the blood. Consequently, the risk of stroke and embolism appears to be negligible and blood thinning medication is not required."

Dr Prabhu is a recognized clinician and scientist whose research centers on understanding mechanisms underlying heart failure. He is especially interested in defining potential therapies geared toward myocardial recovery in heart failure.

"Enrolling the first two female patients into this FDA approved clinical study is a significant milestone for C-Pulse. Despite the fact that females account for nearly 50% of all hospital admissions for heart failure (heart failure affects about 2.5 million women in the US), only 25% of these patients are typically involved in heart failure studies," said Don Rohrbaugh, CEO. "C-Pulse can be an important new therapy for women suffering from heart failure since they typically survive longer than men with the disease but commonly have more illness, more frequent hospitalizations and a poorer overall quality of life."

The 20 patient FDA-approved feasibility clinical trial is being undertaken at six US medical institutions: Northwestern Memorial Hospital, The Ohio State Medical Center, Jewish Hospital, Hershey Medical Center of the Pennsylvania State University, University of Florida School of Medicine and University of Alabama/ Birmingham Medical Center.

### **About Advanced Heart Failure**

Heart failure is a common condition in which the heart becomes unable to pump sufficient blood to meet the body's needs. Over five million people in the US have heart failure and it results in over 300,000 deaths each year. Heart failure is a progressive condition and typically results from damage to the heart muscle arising from a heart attack or virus.

Cardiologists use a 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. Over 1.4 million US heart failure patients are in the Class III or advanced heart failure category which is defined by the limitation of physical activity. 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. A major medical treatment challenge is that the medical regimen and CRT options often stop alleviating symptoms over time, hence the need for C-Pulse heart assist.

### **About Sunshine Heart**

Sunshine Heart (ASX: SHC) ([www.sunshineheart.com](http://www.sunshineheart.com)) is a global medical device company, committed to the commercialization of C-Pulse™ an implantable, non-blood contacting, heart assist therapy for the treatment of people with moderate heart failure. C-Pulse reduces the symptoms of heart failure through the use of counterpulsation technology which enables an increase in cardiac output, an increase in coronary blood flow and reduction in the heart's pumping load. The Company has received approval from the US Food and Drug Administration (FDA) to conduct a 20 person US clinical trial with C-Pulse and patient enrolment has commenced. Sunshine Heart listed on the ASX in September 2004 has a presence in Australia, New Zealand and the United States of America.

For further information, please visit [www.sunshineheart.com](http://www.sunshineheart.com) or contact:

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