



ASX Announcement

Sunshine Heart Prepares for First Clinical Trial in Australia

Key points:

- Sunshine Heart, Inc. receives Ethics Committee Approval from Southern Health Monash Medical Centre, Clayton Victoria, to extend its clinical trial for the C-Pulse heart assist implant.
- Southern Health is one of two Victorian hospitals expected to trial the C-Pulse™ in Australia.
- Should the results from the Australian trial be successful, a larger global trial will be conducted.

Sydney, Australia. 8 November 2005: Sunshine Heart Inc., (ASX: SHC) is preparing for the first clinical trial of the C-Pulse™ heart assist device in Australia, following today's announcement that ethics approval for the clinical trial has been awarded to the Investigators at Southern Health Monash Medical Centre in Melbourne.

The Human Research Ethics Committee at Southern Health has given permission for the recruitment of a first heart failure patient to be implanted with the C-Pulse™ heart assist device, followed by review at three months. This trial is part of a larger trial in Australia and New Zealand involving up to ten patients. The first two patients to be implanted with the C-Pulse™ earlier this year were treated at Auckland City Hospital. Discussions are progressing with other trial centres including another Melbourne centre.

Professor Julian Smith, Principal Investigator and Head of Cardiothoracic Surgery at Southern Health commented: "The treatment options for people in this category of heart failure are limited, so there is a real need for a device such as the C-Pulse™. We are pleased to be able to pioneer the C-Pulse™ technology offered by Sunshine Heart within Australia."

Dr William Peters, Medical Director of Sunshine Heart, added: "The C-Pulse heart assist device is designed to improve the heart function of patients in heart failure by increasing blood supply to the heart muscle and by reducing the pumping work the heart has to do. This is achieved without the device contacting blood, making it safe to turn the device on and off."

Donald Rohrbaugh, CEO of Sunshine Heart Inc. added: "It is great news that Australian centres will participate in the pilot trial of this unique device that is being developed locally."

The long term trial will enrol patients who, despite maximal medical therapy, are repeatedly hospitalised with heart failure. The C-Pulse™ heart assist device is intended to provide therapy to those patients throughout their lives.

More information about the C-Pulse™ heart assist device may be obtained at www.sunshineheart.com.

For further information, please contact:

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ASX AusBiotech Best Practice Reporting Guidelines	
Name of Trial	Pilot clinical trial of the C-Pulse™ as a destination therapy in patients in refractory heart failure
Primary Endpoints	Improvement in Quality of Life, measured by NYHA Class, Minnesota Living with Heart Failure Score, and Six Minute Walk Test at six months post-implant
Secondary Endpoints	Measures of heart size and function as determined by echocardiography, and measures of safety, including all adverse events
Blinding Status	Not blinded
Treatment Method	C-Pulse implantation
No. of Trial Subjects	Up to 10 patients at up to 3 centres
Recruitment Schedule	Approximately 1 patient per month
Selection Criteria	Patients aged 18-80 years, in NYHA Class III or IV heart failure and with no significant ascending aortic disease or aortic valve leakage nor intact aorto-coronary grafts
Partners	Auckland City Hospital and Southern Health (Monash Medical Centre)
Expected Duration	18 months