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Sunshine Heart gets unconditional approval from FDA

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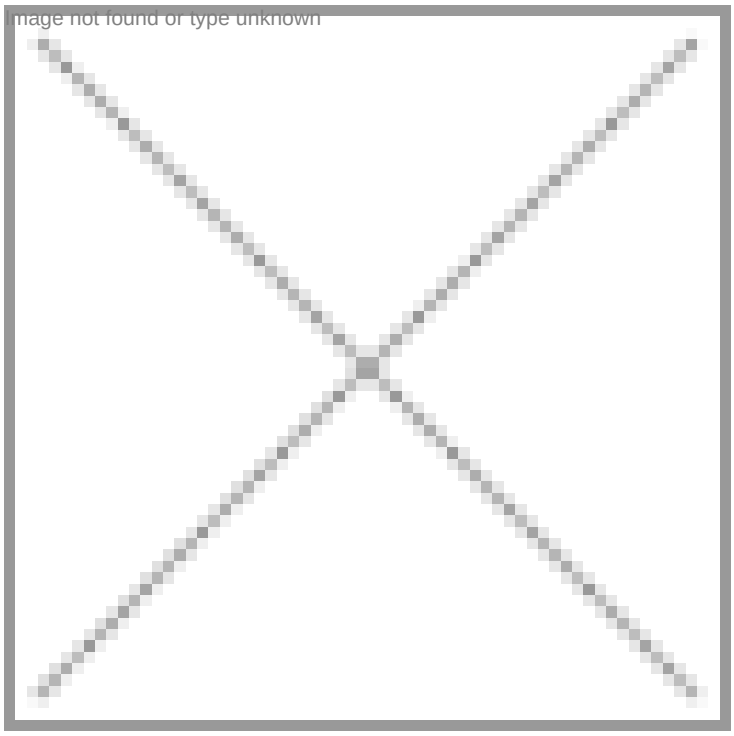

Singapore: Sunshine Heart, a global medical device company focused on innovative technologies for moderate to severe heart failure, has received unconditional approval from the FDA to commence its pivotal US trial for its flagship C-Pulse Heart Assist System.

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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 US 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 US 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 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, division of cardiovascular medicine, Ohio State University Medical Center.