Revolutionary Miniature Blood Pump from CircuLite Successfully Implanted in First Chronic Heart Failure Patient: -Synergy Device Designed to Provide Partial Circulatory Assist in Patients with Chronic Heart Failure-

CircuLite(TM), Inc. today reported the launch of the Company's clinical development program for its Synergy(TM) Pocket Circulatory Assist Device with the successful implantation of the first patient in a European feasibility trial. Synergy is a miniature implantable blood pump, the size of a AA battery, that can be implanted superficially in a pocket, like a pacemaker. The device is designed to provide long-term, partial circulatory support in patients with chronic heart failure. The primary objective of the first-in-man trial is to assess the safety of the device in patients with chronic heart failure who are waiting to receive heart transplants. Bart Meyns, M.D., Ph.D., Professor and Chief of Cardiac Surgery at Gasthuisberg University Hospital (Katholieke Universiteit) in Leuven, Belgium, performed the first implant.

HACKENSACK, N.J. and AACHEN, Germany (PRWEB) August 8, 2007 -- "The first implant of the Synergy device was very successful and the patient has already been discharged home and is doing very well," said Prof. Meyns, Principal Investigator of the trial. "While CircuLite's feasibility clinical study is in a bridge-to-transplant setting, the ultimate need for this type of device will be among those chronic heart failure patients who may not be eligible for a heart transplant. A partial support approach to chronic heart failure treatment may be better able to address the treatment needs and improve the quality of life for this unserved group of patients, who otherwise have no other options."

The CircuLite technology is designed to provide a new treatment option for over two million chronic heart failure patients worldwide who continue to be significantly symptomatic despite appropriate, optimal medical and device-based therapies. While feasibility studies will examine the hemodynamic and clinical effects of the Synergy device in patients that are awaiting heart transplants, CircuLite's ultimate goal is to expand the treatment of heart failure to the chronic, ambulatory patient in order to improve their quality of life by giving them an elective, less-invasive option to increase blood flow from the heart.

"The first-in-man implant of our Synergy device is a significant milestone not only for our company, but for the chronic heart failure community as a whole, especially patients, who we hope will someday benefit from this potentially life-changing therapy," said Paul Southworth, President and CEO of CircuLite. "CircuLite is striving to transform the treatment model for this condition to long-term, partial circulatory support. The commencement of this trial is an achievement that brings together over 11 years of engineering and research and demonstrates our leadership position in this space. This trial will provide us with important data to support our additional planned studies, including a CE Mark trial in Europe, as well as our Investigational Device Exemption (IDE) trials in the United States."

The Phase I study will include up to three European hospitals and will enroll chronic heart failure patients who are awaiting heart transplantation and whose heart function is in a state of decline. Patients will be surgically implanted with the device. The trial will evaluate the safety of the device for up to six months. CircuLite
developed this trial to evaluate Synergy in a surgical, bridge-to-transplant setting in order to collect initial data to establish clinical proof-of-concept; however, the further development of the device will be focused on non-surgical, endovascular implantation for use as a long-term therapy.

"The current trial design is an important first-step for our Synergy device, but our eventual plan is to utilize a minimally invasive procedure and for patients to be implanted with the device sooner, before they have reached the later stages of chronic heart failure. This treatment paradigm would ensure that patients could benefit as much as possible from this long-term therapy," said Daniel Burkhoff, M.D., Ph.D., CircuLite's Medical Director and Adjunct Associate Professor of Medicine at Columbia University Medical School.

About Synergy(TM)

The Synergy Pocket Circulatory Device is a small implantable blood pump designed to provide long-term, partial circulatory support to patients with chronic heart failure. The key component of the Synergy device is the proprietary and patented micro-pump technology acquired after eight years of development at the Helmholtz Institute in Aachen, Germany, one of the world's leading centers for blood pump technology development, in collaboration with Katholieke Universiteit in Leuven, Belgium. The device is designed to be small enough to be implanted subcutaneously in the "pacemaker pocket" through a minimally invasive procedure. Synergy is designed to supplement the heart's native pumping function, potentially increasing blood flow and allowing the heart to rest and potentially recover, possibly improving the quality of life of chronic heart failure patients. The CircuLite technology may provide a new treatment option for millions of chronic heart failure patients worldwide who continue to be significantly symptomatic despite appropriate, optimal medical therapy.

About CircuLite(TM)

CircuLite is developing a miniature blood pump, designed to be placed superficially like a pacemaker, for the long-term treatment of chronic heart failure. The Synergy Pocket Circulatory Assist device is designed to rest a failing heart by supplementing its natural function. By providing long-term circulatory assist on a minimally invasive platform, CircuLite's Synergy has the potential to transform the management of chronic heart failure and improve the quality of life for millions of patients and their families. For more information on CircuLite and the Synergy Pocket Circulatory Assist device, visit our website at www.CircuLite.net.


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