



CIRCULITE DEMONSTRATES LONG-TERM IMPROVEMENTS AND HEMODYNAMIC BENEFITS WITH SYNERGY® PARTIAL CIRCULATORY SUPPORT IN CHRONIC HEART FAILURE PATIENTS

- Late-breaking Abstract Presented at 58th Annual Scientific Session of the American College of Cardiology -

- AA battery-sized pump offers less-invasive alternative to full-support LVADs -

ORLANDO, F.L. and SADDLE BROOK, N.J. (March 30, 2009) – [CircuLite, Inc.](#) today announced the presentation of positive clinical data for its Synergy® Pocket Micro-pump for chronic heart failure. The data demonstrates that long-term, partial circulatory support with Synergy yielded statistically significant hemodynamic benefits and sustained improvements in cardiac function with evidence of myocardial recovery in patients with chronic heart failure. The presentation was given by Daniel Burkhoff, M.D., Ph.D., Chief Medical Officer of CircuLite and Adjunct Associate Professor of Medicine at Columbia University Medical School, at the [58th Annual Scientific Session of the American College of Cardiology](#) in the Late-Breaking Clinical Trials Emerging Technologies session. Synergy is a micro-blood pump, the size of a AA battery, that can be implanted superficially in a “pacemaker-like” pocket. Synergy is the first and smallest device designed for partial circulatory support (up to 3L/min) and long-term use in patients with Class IIIb and early Class IV heart failure.

“These data show that partial circulatory support with the Synergy device effectively unloads the heart and can interrupt the progressive hemodynamic deterioration that typically occurs in the later stages of chronic heart failure,” said Dr. Burkhoff. “We are particularly encouraged with the finding that patients in this study showed signs of myocardial recovery, suggesting that treatment with this device can yield long-term improvements in clinical status and quality of life, not only in hemodynamic parameters as we have now shown. A smaller, less-invasive device like Synergy could expand the eligible patient population for circulatory support devices and may address the limitations of left ventricular assist devices, which are associated with a major surgery and significant adverse events.”

“Synergy represents a new approach to mechanical circulatory support, which we believe may be a breakthrough in chronic heart failure management by enabling earlier, less-invasive treatment for more patients,” said Paul Southworth, President and CEO of CircuLite. “We are excited by the impressive results emerging from our ongoing study of the long-term use of Synergy and believe that the data support our ultimate goal for the device, which is long-term, partial support in patients with Class IIIb/IV chronic heart failure. We look forward to receiving CE Mark approval and our commercial launch of Synergy in Europe later this year.”

The presentation details results for 16 patients (13 males) who were implanted with Synergy. Significant improvements in hemodynamics were observed in the first day of support. Additionally, 8 patients have

since completed their follow-up right heart catheterization at a mean of 11 weeks, and the data demonstrate that the significant hemodynamic improvements were sustained. Mean arterial pressure increased from 68 mmHg to 81 mmHg (p=0.02) and mean cardiac index increased from 2.0 to 2.8 L/min/m² (p=0.01). Large reductions in mean capillary wedge pressure were observed (29 to 17 mmHg, p=0.003). In addition, mean peak VO₂ increased from 9.6 to 14.1 ml/kg/minute. The duration of patient support with Synergy averaged 90 days, with the longest support period of 213 days. At three months, 81 percent (13/16) of patients were alive and nine received heart transplants. No device related deaths or strokes have occurred.

About Synergy®

The Synergy® Pocket Micro-pump represents a new approach to mechanical circulatory support that is designed to transform chronic heart failure management by providing a less-invasive, elective treatment option for patients before their disease state becomes emergent. Synergy is the first implantable system designed to provide partial circulatory support (PCS) for long-term use in millions of unserved patients that have NYHA Class IIIb/early IV disease.

CircuLite's patented micro-pump provides up to 3L/min of flow, which increases total cardiac output, offloads the heart, allowing it to rest, and potentially enables beneficial recovery of heart function. The size of a AA battery, the device is small enough to be implanted subcutaneously in a "pacemaker-like" pocket through a minimally-invasive procedure.

About CircuLite®

CircuLite is transforming heart failure treatment with the development of minimally-invasive devices for long-term partial circulatory support (PCS). By enabling a proactive and lower-risk treatment approach by supplementing a patient's native pumping capacity, CircuLite has the potential to improve the quality of life for millions of chronic heart failure patients and their families. CircuLite's pipeline of PCS devices is lead by the Synergy® Pocket Micro-pump, the world's smallest implantable blood pump currently in a CE Mark clinical trial. Next-generation Synergy micro-pumps include an endovascular system, a fully-implantable system and a pediatric system. For more information on CircuLite and the Synergy Pocket Micro-pump devices, visit our website at www.CircuLite.net.

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