



CIRCULITE® RECEIVES CONDITIONAL IDE APPROVAL FOR SYNERGY® CIRCULATORY SUPPORT SYSTEM FEASIBILITY TRIAL

**Minimally-Invasive System Designed To Reverse Heart Failure Fills Treatment Gap
for Ambulatory Chronic Heart Failure Patients**

SADDLE BROOK, NJ (March 5, 2013) – [CircuLite®, Inc.](#) today announced that it has received conditional approval from the United States Food and Drug Administration (FDA) of an Investigational Device Exemption (IDE) for its lead product, the [SYNERGY® Circulatory Support System](#), a minimally-invasive device designed to reverse the symptoms of heart failure in ambulatory chronic heart failure patients.

Heart failure is a progressive disease. Once patients deteriorate to the point of experiencing persistent, severe symptoms despite receiving optimal medical treatment (ACE inhibitor, beta blocker, defibrillator and/or pacemaker), their options are very limited. SYNERGY is the world's smallest circulatory support pump – approximately the size and weight of a AA battery - and is designed to work in synergy with the native heart to improve blood flow to the brain and body, rather than replace the heart's function. The procedure is minimally invasive and does not require open heart surgery, eliminating the need for cardiopulmonary bypass. In a European CE Mark clinical study, SYNERGY was shown to improve hemodynamics, exercise capacity and overall quality of life in ambulatory chronic heart failure patients (INTERMACS ≥ 4 or NYHA Class III/IV).

"Many ambulatory chronic heart failure patients have a very poor quality of life today," said Daniel Burkhoff, MD, PhD, Chief Medical Officer of CircuLite and Adjunct Associate Professor of Medicine at Columbia University Medical School. "Despite running the gamut of heart failure treatment, they are severely restricted by their symptoms, yet are not sick enough to justify more invasive surgical treatment options. SYNERGY has the potential to reverse many of the abnormalities that underlie those symptoms, with the goal of improving a patient's activity level and quality of life."

With receipt of conditional IDE approval, CircuLite plans to commence its U.S. clinical trial evaluating the use of the SYNERGY Circulatory Support System for long-term support in ambulatory chronic heart failure patients (INTERMACS ≥ 4) who remain symptomatic despite optimal medical management. The IMPACT Trial (Safety Evaluation of the CircuLite SYNERGY Circulatory Assist Device in a Non-Inotrope Dependent, Ambulatory Patient with End-Stage Chronic Heart Failure: A Pilot Study) is a 20-patient feasibility trial that will be conducted at seven U.S. clinical sites.

"Beginning our U.S. feasibility trial marks a significant milestone for the company, and is the first step on our path to providing a new treatment option to tens of thousands of U.S. ambulatory chronic heart failure patients who have no other options today," said Paul Southworth, Chief Executive Officer of CircuLite.

The minimally-invasive SYNERGY procedure is performed through a mini-thoracotomy and the micro-pump is implanted in a shallow "pacemaker pocket". It requires no bypass and enables a quick recovery, offering the potential to impact the economics of treating ambulatory chronic heart failure patients.

SYNERGY received [CE Mark](#) in September 2012 and is currently conducting a controlled commercial rollout in Europe.

About the SYNERGY® Circulatory Support System

The SYNERGY Circulatory Support System is a micro-blood pump that provides up to 4.25 liters of blood per minute and reduces the heart's workload, while improving blood flow to vital organs. The system is surgically implanted using a mini-thoracotomy and the micro-pump is placed in a pacemaker-like pocket. The system's less invasive procedure is intended to reduce the surgical risks associated with cardiopulmonary bypass support. In addition, SYNERGY is intended to reduce rehospitalizations associated with heart failure symptoms. SYNERGY is designed and manufactured in Aachen, Germany.

About CircuLite®

CircuLite is developing disruptive solutions to improve the treatment of heart failure. The Company's technologies work in conjunction with the heart to enhance clinical outcomes and improve quality of life. SYNERGY, which received CE Mark in 2012, features the smallest surgically-implanted blood pump for long-term use in ambulatory chronic heart failure patients not responding to optimal medical treatment. The company is developing a portfolio of minimally-invasive systems based on its proprietary micro-pump platform, including an endovascular system, a right-heart system, a pediatric system and an all-support system. For more information, visit our website at www.circulite.net.

CAUTION: Investigational Device. Limited by United States Law to Investigational Use Only.
CircuLite® and SYNERGY® are registered trademarks of CircuLite, Inc. in the United States.

###

MEDIA CONTACT:

Michelle McAdam, Chronic Communications
michelle@chronic-comm.com, (310) 902-1274