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CellAegis Devices Announces Clinical Program to Use the Company's Noninvasive autoRIC™ Device for Chronic Remote Ischemic Conditioning (CRIC) following Acute Myocardial Infarction (AMI)

-- Phase II, randomized, placebo-controlled, multi-center study will measure the primary efficacy endpoint of reduction in ventricular remodeling post-percutaneous coronary intervention (PCI) --

-- Patient enrollment to initiate by the second quarter of 2013 at three leading Toronto cardiac care facilities: Peter Munk Cardiac Centre, Toronto General Hospital, University Health Network; St Michael's Hospital, and Sunnybrook Health Sciences Centre --

Toronto, Ontario, February 27, 2013 --- CellAegis Devices, Inc., announced today that it has received an Investigational Testing Approval (ITA) from Health Canada that allows the initiation of clinical testing in Canada of the Company's autoRIC™ Device for Chronic Remote Ischemic Conditioning (CRIC). In a Canadian Institutes of Health Research (CIHR)-sponsored Phase II, randomized, double-blind, placebo-controlled, multi-center clinical study, CRIC will be evaluated for its ability to reduce adverse left ventricular remodeling following primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI).

This is the third clinical trial to incorporate CellAegis' autoRIC Device. In August 2012, the Company announced the initiation of an Aarhus University-sponsored clinical trial program in Europe utilizing the autoRIC Device for patients with evolving STEMI; the trial is measuring the potential to reduce major adverse coronary events and hospitalizations. In November 2012, the Company also announced an investigator-sponsored clinical trial at Princess Margaret Hospital in Toronto to evaluate the ability of the autoRIC Device to reduce acute kidney injury induced by intraoperative renal ischemia during partial nephrectomy.

CellAegis' autoRIC Device provides a noninvasive, safe and accurate device to automate RIC at the point of care. The Device is CE marked and has been developed for acute care applications in the ambulance, emergency room and other hospital settings, as well as for use in the home as directed by a healthcare professional.

"While emergent PCI greatly improves short-term outcomes in patients, survivors of an AMI can be at significant risk of developing adverse myocardial remodeling, which is characterized by progressive changes in structure and function which can progress to clinical heart failure," commented Christopher Overgaard, M.D., Study Principal Investigator and Interventional Cardiologist, Peter Munk Cardiac Centre. "Even as mortality from an AMI has decreased in developed nations, the number of patients with congestive heart failure is increasing. New approaches such as CRIC, which has the added advantage of being noninvasive, need to be investigated to determine their potential role in advancing treatment and helping improve patient outcomes. I look forward to the progress of the clinical program and initiation of patient enrollment later this year."

Rocky Ganske, CEO of CellAegis Devices, stated "This post-PCI trial will be the first to determine the potential of RIC using the autoRIC™ Device in a chronic setting for the treatment of cardiovascular disease. We believe this approach, pending the results of the study, could have a significant impact in preventing heart failure in patients who have suffered a myocardial infarction. The Phase II trial also is the third study to incorporate the autoRIC™ Device, and we are pleased to see growing recognition of the potential of our Device in facilitating RIC in diverse settings and applications."

The Phase II study design for the clinical program calls for the enrollment of 82 adult patients treated emergently with primary PCI for STEMI involving the Left Anterior Descending (LAD) artery within 12 hours of onset of symptoms of a heart attack. Patients will be randomized 1:1 to either: a) a treatment group (CRIC) receiving CRIC using CellAegis' autoRIC Device programmed to give four cycles of controlled blood occlusion (ischemia) in a limb via inflation of the Device cuff to a pressure of 200 mm Hg for 5 minutes, followed by resumed blood flow (reperfusion), or b) a control group (SHAM) wearing an identical autoRIC Device, which is inflated only to 10 mm Hg such that no limb ischemia occurs. All patients will have initiated CRIC or SHAM using CellAegis' autoRIC Device prior to the PCI procedure and then will use the Device once-daily (4 cycles each day) for a 28-day period post-PCI.

The primary endpoint of the study is to assess change from baseline in left ventricular end diastolic volume at three months post-PCI via cardiac magnetic resonance imaging (MRI). Secondary endpoints include: change from baseline in left ventricular ejection fraction (LVEF) and infarct mass at 3 months post-PCI (assessed by cardiac MRI); inflammatory biomarkers at 24 hours after revascularization and over the 28-day treatment period, and the rate of major adverse cardiac events (MACE) and mortality at 6 and 12 months post-MI.

The preclinical study (published in May 2011) concluded that although a single early episode of remote perconditioning reduces infarct size, repeated remote CRIC further reduced adverse LV remodeling and improved survival in a dose-dependent fashion.[i]

About RIC

Remote ischemic conditioning uses sequences of short, controlled periods of blood occlusion (ischemia) in a limb followed by resumed blood flow (reperfusion). By activating innate mechanisms of metabolic protection in the body, RIC has been shown to reduce the larger injury from ischemia reperfusion to heart and other organs, including myocardial infarctions, cardiac surgery, stroke, trauma, and organ transplantation. Based on studies in over 14,000 individuals in more than 85 ongoing and completed clinical trials worldwide, as well as key findings reported at medical conferences and published in leading peer-reviewed publications, data have shown that RIC can reduce heart damage by up to 40-50% in an evolving heart attack,[ii] as well as improve left ventricular ejection fraction in left anterior descending coronary artery (LAD) infarction,[iii] and is associated with reduced subsequent cardiovascular events late after PCI,[iv] and most recently, reduced incidences of contrast-medium-induced nephropathy.[v]

About CellAegis

CellAegis Devices, Inc., based in Toronto, Canada, is poised for EU market introduction in parallel with a broad international clinical testing program of the Company's proprietary, automated, noninvasive autoRIC™ Device for Remote Ischemic Conditioning (RIC). Placed around the arm, CellAegis' autoRIC Device allows for the first time, simple, consistent, reliable and cost-effective automation of RIC at the point of care, including acute care applications in the ambulance, emergency room and other hospital settings, or for treatment in the home as directed by a healthcare professional. The autoRIC Device is highly portable and time-efficient, delivering four cycles of simple-to-administer treatment in less than 40 minutes. The device is compatible with current standard-of-care treatments.

CellAegis has extensive intellectual property protections for its autoRIC Device. In late 2011, CellAegis received ISO 13485 certification which covers the design, development, manufacturing and distribution of medical devices. For more information on CellAegis and the autoRIC Device, please visit www.cellaegisdevices.com.

The autoRIC Device is not approved for commercialization in the U.S.

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iii Munk K *et al*. Remote ischemic conditioning in patients with myocardial infarction treated with primary angioplasty: Impact on left ventricular function assessed by comprehensive echocardiography and gated single-photon emission CT. *Circ Cardiovasc Imaging* 2010;**3**:656-662; DOI:10.1161/CIRCIMAGING.110.957340

iv Hoole SP *et al*. Cardiac remote ischemic preconditioning in coronary stenting (CRISP Stent) study: A prospective, randomized control trial. *Circulation* 2009;**119**:820-827; DOI:10.1161/CIRCULATIONAHA.108.809723

v Er F *et al*. Ischemic preconditioning for prevention of contrast-medium-induced nephropathy: Randomized pilot RenPro-Trial (Renal Protection Trial). *Circulation* 2012;**126**:296–303; 10.1161/CIRCULATIONAHA.112.096370