

CellAegis Devices Inc.
139 Mulock Ave., 1st Floor
Toronto, Ontario M6N 1G9

Main Office: 647-722-9601
Fax: 647-722-9553
www.cellaegis.com



CellAegis Devices Announces Initiation of Clinical Testing of Remote Ischemic Conditioning (RIC) Using the autoRIC™ Device for Patients Undergoing Partial Nephrectomy

-- Clinical program to take place at University Health Network - Princess Margaret Hospital in Toronto; trial will evaluate ability of RIC to reduce acute kidney injury induced by intraoperative renal ischemia --

-- Benefits of RIC in diverse medical settings recently reported at The Transcatheter Cardiovascular Therapeutics (TCT) conference and at the American Heart Association's (AHA) Scientific Sessions --

-- Long-term outcomes data show significant morbidity/mortality benefit of RIC therapy in diverse applications, including cardiac surgery, evolving myocardial infarction, and elective coronary intervention --

Toronto, Ontario, November 12, 2012 -- CellAegis Devices, Inc., announced today that it has received an Investigational Testing Approval (ITA) from Health Canada which allows the initiation of clinical testing in Canada of the Company's autoRIC™ Device for remote ischemic conditioning (RIC). In a pilot clinical trial sponsored by Michael Jewett, M.D., of the University Health Network - Princess Margaret Hospital in Toronto, RIC will be evaluated for its ability to reduce acute kidney injury induced by intraoperative renal ischemia during partial nephrectomy. This is the second clinical trial to incorporate CellAegis' autoRIC Device. In August, the Company announced the initiation of an Aarhus University-sponsored clinical trial program in Europe utilizing the autoRIC Device for patients with evolving ST-elevation myocardial infarction (STEMI).

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.

The study design for the Toronto clinical program calls for the enrollment of 24 adult patients with stage T1 renal cell carcinoma (RCC) scheduled to undergo partial nephrectomy. Patients will be randomized 1:1 to either a) a treatment group receiving RIC using CellAegis' autoRIC Device, or b) a control group wearing a standard, uninflated blood pressure cuff. For patients in the treatment group, RIC will be initiated after anesthesia induction and prior to the surgical procedure. For all patients, postoperative measurements will include serum creatinine, eGFR, and serum NGAL (a renal injury biomarker), which will be measured at 2, 6, and 24 hours after reperfusion following the surgical procedure. The goal of the study is to determine the ability of protective RIC to reduce acute kidney injury induced by intraoperative renal ischemia during partial nephrectomy (PN), potentially resulting in better postoperative renal function.

Rocky Ganske, CEO of CellAegis Devices, stated, “In 2012, we have seen both increasing physician awareness of the value of RIC and adoption of our technology in clinical programs. The trial at Princess Margaret Hospital brings the autoRIC Device to a new set of clinicians and key opinion leaders, and extends our geographic reach following the initiation of clinical testing of RIC in the ongoing STEMI study in the EU.”

Mr. Ganske continued, “In addition to the ongoing studies, we anticipate seeking regulatory approval to begin our own clinical program in the U.S. in the near term. Our primary focus remains in cardiovascular indications, and we believe RIC has the potential to provide benefit for patients across a wide range of indications in this arena. Bringing this important treatment to patients is our top priority.”

RIC Long-Term Data Featured at AHA and TCT Conferences

Recently, presentations featured long-term clinical outcomes for RIC at two major cardiology conferences – The Transcatheter Cardiovascular Therapeutics (TCT) conference and the American Heart Association’s (AHA) Scientific Sessions.

- **RIC reduces 5-yr major adverse cardiovascular event (MACE) rate by 46% in evolving MI:** In a presentation at TCT 2012, TCT-63. Remote Ischemic Preconditioning Improves Long-term Clinical Outcome in Patients Undergoing Primary Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction (<http://content.onlinejacc.org/mobile/article.aspx?articleid=1383336>), researchers from Aarhus University in Denmark reported that RIC therapy given at the time of MI reduced MACE rates by 46%, from 24.3% in the control group to 13% in the RIC group (HR=0.46). MACE comprised all-cause mortality (66% reduction), myocardial reinfarction (40% reduction), and hospitalization for heart failure (40% reduction). These are the long-term outcomes data from a study in 333 patients, originally published in Lancet in 2010ⁱ.
- **RIC improves mortality outcomes in cardiac surgery:** In a presentation at AHA 2012, Presentation 14034: Prognostic Benefit from Remote Ischemic Preconditioning in 300 Patients Undergoing Coronary Artery Bypass Surgery: A Randomized Controlled Trial, researchers from Essen University in Germany reported that mortality at 4 year follow up was 3.6% in the control arm, and 0.6% in the RIC arm. Kaplan-Meier overall survival (P=0.03) and event-free survival (P=0.04) were better in the RIC group, confirming that RIC not only provided myocardial protection, but also superior survival in patients undergoing coronary artery bypass surgery.
- **RIC reduces 6 yr major adverse cardiac and cerebrovascular event (MACCE) rate by 36% in Elective Angioplasty:** In a presentation at AHA 2012, Presentation 16182: Remote Ischemic Preconditioning Improves Outcome Out to 6-years Following Elective Percutaneous Coronary Intervention: the CRISP-Stent Trial, researchers from Cambridge, England, reported that RIC treatment resulted in a statistically significant 35% reduction in MACCE (Major Adverse Cardiac and Cerebral Events) rates, from 37.1% in the control group to 24.2% in the RIC group (p=0.039). These results show that NNT=8 (NNT is the number of patients needed to get the treatment to show the benefit). The results confirm the initial benefits seen in the CRISP Trialⁱⁱⁱ, in which patients had lower procedural levels of myocardial injury and chest pain, as well as a reduction in 6-month MACCE rates.

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,ⁱ as well as improve left ventricular ejection fraction in left anterior descending coronary artery (LAD) infarction,ⁱⁱ and is associated with reduced subsequent cardiovascular events late after PCIⁱⁱⁱ and most recently, reduced incidences of contrast-medium-induced nephropathy.^{iv}

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 <http://www.cellaegisdevices.com>.

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

i Bøtker HE et al. Remote ischaemic conditioning before hospital admission, as a complement to angioplasty, and effect on myocardial salvage in patients with acute myocardial infarction: a randomized trial. *Lancet* 2010;**375**:727-34; DOI:10.1016/S0140-6736(09)62001-8

ii 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

iii Hoole SP et al. Cardiac remote ischemic preconditioning in coronary stenting (CRISP Stent) study. *Circulation* 2009;**119**:820-827; DOI:10.1161/CIRCULATIONAHA.109.191747

iv Er F et al. Circulation, Ischemic Preconditioning for Prevention of Contrast-Medium-Induced Nephropathy: Randomized Pilot RenPro-Trial (Renal Protection Trial) *Circulation* **126**, 296-303 (2012). 10.1161/CIRCULATIONAHA.112.096370

Contacts:

Corporate Development and Investors:
CellAegis
Rocky Ganske, 647-722-4735
CEO
rganske@cellaegisdevices.com

For Media:
Burns McClellan
Justin Jackson, 212-213-0006
jjackson@burnsmc.com