CellAegis Devices Receives Marketing Authorization from Health Canada for the autoRICT Device to Provide Non-Invasive Remote Ischemic Conditioning (RIC)

The Associated Press

CellAegis Devices, Inc. announced today that it has received marketing authorization from Health Canada that allows for the commercial introduction in Canada of the Company's autoRICT Device for Remote Ischemic Conditioning (RIC).

Health Canada has granted a Medical Device Class III license for use of the autoRIC Deviceto provide non-invasive RIC for adult patients undergoing cardiothoracic surgery or interventional cardiothoracic procedures, as well as for patients with evolving myocardial infarction. Offering a safe and accurate method to automate RIC at the point of care, CellAegis' autoRIC Device is intended to reduce tissue injury from heart procedures or heart attacks in a hospital or ambulance setting or in the home as directed by a healthcare professional. CellAegis further announced that the company will exhibit to an international audience at the American College of Cardiology's 62nd Annual Scientific Session & Expo taking place in San Francisco from March 9-11, 2013. The autoRIC Device is not available for sale or use in the United States.

In a joint statement, the founders of CellAegis, Drs. Andrew Redington, Head of Cardiology, The Hospital for Sick Children (SickKids) in Toronto, and Christopher Caldarone, Professor and Chair of the Division of Cardiac Surgery, University of Toronto, and Staff Cardiovascular Surgeon at SickKids, commented, "Remote ischemic conditioning activates innate mechanisms of metabolic protection and has the potential to revolutionize the treatment of cardiovascular disease. We believe a reliable and automated method of providing RIC offers the potential for significant reductions in myocardial injury with an extremely favorable risk/benefit ratio at a fraction of the cost of other high-tech therapies benefiting the patient, payor, and the provider. We are excited that patients now will have access to this technology throughout Canada." The intellectual property that has arisen from groundbreaking work performed by researchers at Sickkids has been exclusively licensed to CellAegis who continue to work collaboratively to mutual benefit.

In Canada, the leading cause of hospitalization continues to be heart disease and stroke, with almost three million hospitalizations per year.i There are an estimated 1.3 million people in Canada living with heart disease, who have a 5-7 times greater risk of experiencing a myocardial infarction or death.ii There are 70,000 heart attacks per year, or one heart attack every 7 minutes. There are also 50,000 new cases of heart failure per year, and half a million Canadians are living with heart failure.iii Heart disease costs the Canadian economy more than $20 billion per year in direct and indirect costs.iv Rocky Ganske, CEO of CellAegis Devices, said, "The

Health Canada authorization, following the receipt of a CE Mark in Europe in 2012, further validates the safety of the autoRIC Device. We are planning commercialization in the second half of this year and also look forward to the continued incorporation of the autoRIC Device in multiple clinical trials throughout the global cardiology community.

We believe these trials will help augment the growing body of evidence in support of RIC for diverse applications in cardiovascular disease." In February 2013, CellAegis announced that it had received an Investigational Testing Approval (ITA) from Health Canada allowing for the initiation of clinical testing in Canada of the Company's autoRIC Device for Chronic Remote Ischemic Conditioning (CRIC) following acute myocardial infarction (AMI). The Canadian Institutes of Health Research (CIHR)-sponsored study is designed to evaluate the ability of the autoRIC Device to reduce adverse left ventricular remodeling following primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI). In November 2012, CellAegis 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. In August 2012, the Company also 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.

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,v as well as improve left ventricular ejection fraction in left anterior descending coronary artery (LAD) infarction,vi and is associated with reduced subsequent cardiovascular events late after PCI,vii and most recently, reduced incidences of contrast-medium-induced nephropathy.viii A 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.ix About CellAegis CellAegis Devices, Inc., based in Toronto, Canada, is poised for both EU and Health Canada market introductions in parallel with a broad international clinical testing program of the Company's proprietary, automated, noninvasive autoRICT 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.

i Canadian Institute for Health Information. Inpatient hospitalizations and average length of stay trends in Canada, 2003-04 and 2004-05. November 30, 2005. https://secure.cihi.ca/free_products/hmdb_analysis_in_brief_f.pdf
ii Tracking Heart Disease and Stroke in Canada. Released June 2009. http://www.phac-aspc.gc.ca/publicat/2009/cvd-avc/index-eng.php
iii Ross H et al. Treating the right patient at the right time: Access to heart failure care. Canadian Journal of Cardiology 2006;22:749-54; DOI:10.1016/S0828-282X(06)70290-2
iv Conference Board of Canada. The Canadian Heart Health Strategy: Risk Factors and Future Cost Implications. Report February 2010. http://www.conferenceboard.ca/e-library/abstract.aspx?did=3447
v Botker HE etal. Remote ischaemic conditioning before hospital admission, as a complement to angioplasty, and effect on myocardial salvage in patients with acute myocardial infarction: A randomised trial. Lancet 2010;375:727-734; DOI:10.1016/S0140-6736(09)62001-8
vi Munk K etal. 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. CircCardiovascImaging 2010;3:656-662; DOI:10.1161/CIRCIMAGING.110.957340
vii Hoole SP etal. 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
viii Er F etal. 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
ix Wei M et al. Repeated remote ischemic postconditioning protects against adverse left ventricular remodeling and improves survival in a rat model of myocardial infarction. Circulation Research 2011;108:1220-1225; DOI:10.1161/CIRCRESAHA.110.236190