CellAegis Devices Announces First Clinical Program to Use the Company's autoRIC™ Device for Remote Ischemic Conditioning during Myocardial Infarction

The Associated Press

TORONTO--(BUSINESS WIRE)--Aug 27, 2012--CellAegis Devices, Inc., announced today the first clinical program to evaluate the use of the Company's autoRIC™ Device for remote ischemic conditioning (RIC) in 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. CellAegis' autoRIC 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 chronic treatment in the home.

In a clinical program led by Hans Erik Bøtker, M.D., Ph.D., University Hospital in Aarhus, Denmark, a randomized study in patients with evolving STEMI will measure the benefit of RIC using CellAegis' autoRIC Device on one year Major Adverse Coronary Events (MACE) and Hospitalizations for Heart Failure (HHF) prior to percutaneous coronary intervention (PCI). The international, multi-center study is being conducted at sites in Europe and the U.S. and is expected to enroll 2,400 adult patients with a suspected first acute myocardial infarction (heart attack). Patients will be randomly assigned in a 1:1 ratio to receive primary PCI or primary PCI with RIC. The autoRIC Device will deliver four cycles (5-min inflation and 5-min deflation) of intermittent arm ischemia (RIC) during transport to a hospital. Secondary trial outcomes will measure the benefit of RIC in reduction of infarct size at 30 days and 6 months, and on 6 month HHF.

Dr. Bøtker, Lead Study Investigator and Professor, Department of Cardiology, Skejby Hospital, University Hospital in Aarhus, commented, "RIC has been shown to activate innate mechanisms of metabolic protection, with the potential to transform the treatment of ischemic-related reperfusion injury. Prior studies in STEMI patients have demonstrated that RIC performed before hospital admission or potential interventions, such as PCI or cardiac surgery, safely increases myocardial salvage. We are pleased to continue our groundbreaking program studying the potential of RIC in multiple patient settings and look forward to the results of this large outcomes study." Rocky Ganske, CEO of CellAegis Devices, stated, "We are very excited Dr. Bøtker is leading the first RIC study to incorporate our autoRIC Device. A key advantage of this technology is that it allows simple, consistent, reliable and cost-effective automation of RIC. We look forward to expanding the use of the autoRIC Device to additional clinical studies in the U.S. and Europe where patients at risk of reperfusion injury can benefit from ischemic conditioning." 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 ischemic reperfusion to cardiac and other organs, including myocardial infarctions, cardiac surgery, stroke, trauma, and organ transplantation. Based on studies in over 10,000 individuals in more than 66 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, 1 as well as improve left ventricular ejection fraction in left anterior descending coronary artery (LAD) infarction, 2 and is associated with reduced subsequent cardiovascular events late after PCI 3 and most recently, reduced incidences of contrast-induced nephropathy. 4 In July 2012, CellAegis received a CE Mark for the autoRIC Device. Receipt of the CE Mark Certification from AMTAC Certification Services Limited in Milton Keynes, England (a subsidiary of Intertek) demonstrates that the autoRIC Device conforms to the European Medical Device Directive 93/42/EEC, which allows a company to market and sell products in the 32 member countries and seven cooperating countries of the European Economic Area (EEA).

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 chronic treatment in the home. 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.cellaegis.com/.

The autoRIC Device is not yet cleared for sale in the U.S.

1 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 randomised trial. Lancet 2010; 375:727-34; DOI:10.1016/S0140-6736(09)62001-8 2 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 3 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 4 Er F et al. Circulation, Ischemic Preconditioning for Prevention of Contrast-Medium-Induced Nephropathy: Randomized Pilot RenPro-Trial (Renal Protection Trial)

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