CellAegis Devices Receives CE Mark for autoRIC™ Device in the European Union

The Associated Press

TORONTO--(BUSINESS WIRE)--Jul 18, 2012--CellAegis Devices, Inc., announced today that it has received a CE Mark for the Company's autoRIC™ Device, which for the first time allows simple, consistent, reliable and cost-effective automation of remote ischemic conditioning (RIC) at the point of care. CellAegis' autoRIC Device has been developed for acute care applications in the ambulance, emergency room and other hospital settings, or for chronic treatment in the home. 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).

Rocky Ganske, CEO of CellAegis Devices, stated, "The CE Mark validates the safety of the autoRIC Device, and we are looking forward to starting a broad clinical testing program in the EU and United States later this year to add to the growing body of evidence in support of RIC. We believe the autoRIC Device has the potential to revolutionize the treatment of ischemic-related reperfusion injury by providing a noninvasive and reliable therapeutic option to be used alongside current standards of care." In the United States, there are an estimated 13.1 million annual incidences of myocardial infarctions (heart attack), chest pain, cardiac revascularization procedures and surgical applications. Altogether, there are an estimated 23.4 million people in the U.S. living with prior heart attacks, angina and heart failure. An additional 57 million Americans are living with cardiovascular disease and have a 5-7 times greater risk than the general population of experiencing a myocardial infarction or death.

Remote ischemic conditioning uses sequences of short, controlled periods of reduced or no blood flow (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 damage from ischemic reperfusion injury 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 percutaneous coronary interventions (PCI) 3 and most recently, reduced incidences of contrast-induced nephropathy. 4 In the second half of this year, CellAegis is initiating an international trial of the autoRIC Device in the EU and U.S. in patients who will

undergo elective PCI and cardiac surgery, including coronary artery bypass graft (CABG) surgery. The randomized study will measure decrease in heart damage and mortality in over 1000 patients to be enrolled in multiple clinical centers in the UK, Denmark, Germany and the U.S.

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)
CONTACT: Corporate and Investor Interest: CellAegis Rocky Ganske, CEO, 647-722-4735 rganske@cellaegisdevices.com or For Media: Burns McClellan, 212-213-0006 Justin Jackson jjackson@burnsmc.com or Maroussia Czarny mczarny@burnsmc.com
KEYWORD: UNITED KINGDOM UNITED STATES EUROPE NORTH AMERICA CANADA GERMANY NEW YORK INDUSTRY KEYWORD: HEALTH BIOTECHNOLOGY CLINICAL TRIALS MEDICAL DEVICES OTHER HEALTH MEDICAL SUPPLIES GENERAL HEALTH SOURCE: CellAegis Devices, Inc. PUB: 07/18/2012 08:00 AM/DISC: 07/18/2012 08:00 AM http://www.businesswire.com/news/home/20120718005178/

autoric%E2%84%A2-device-european-union